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U.S. Department of Health, Education, and Welfare
FOOD AND DRUG ADMINISTRATION

**NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD,
DRUG, AND COSMETIC ACT**

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

7321-7360

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription;" and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b) (1) and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., January 28, 1964.

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VIOLATIVE SALES OF PRESCRIPTION DRUGS

7321. (F.D.C. No. 47850. S. Nos. 5-781 R, 5-783 R, 5-785 R.)

INDICTMENT RETURNED: 10-16-62, S. Dist. W. Va., against William H. Crain, t/a Sam's Ashland Truck Stop, Henderson, W. Va., and Charles W. Houser, James R. Bost, and Fred G. Culp (employees).

CHARGE: Between 10-20-60 and 6-2-61, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Not guilty by Crain to 2 counts; guilty by Houser, Bost and Culp to 1 count each.

DISPOSITION: 5-6-63. Houser and Bost—imprisonment for 9 months; Culp—imprisonment for 7 months.

On 5-1-63, the case against William H. Crain came on for trial before court and jury and, on 5-6-63, the jury rendered a verdict of not guilty.

7322. (F.D.C. No. 48178. S. Nos. 5-701/2 T, 5-704/5 T.)

INFORMATION FILED: 4-2-63, W. Dist. Va., against O. C. Davidson, t/a Cloyds Mountain Truck Stop, Dublin, Va., Thelma Irene Carter, and Mary Catherine Richardson (employees).

CHARGE: Between 3-2-62 and 3-8-62, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty by Davidson to 4 counts; by Miss Richardson to 2 counts; not guilty by Mrs. Carter.

DISPOSITION: 5-7-63. Davidson—\$500 fine and probation for 3 years; Miss Richardson—probation for 3 years; Mrs. Carter was found not guilty by the jury.

7323. (F.D.C. No. 47847. S. Nos. 23-815/18 T, 23-861 T.)

INFORMATION FILED: 9-4-62, Dist. Colo., against Truck Denver, Denver, Colo. (a partnership), and George M. Dick (partner and general manager), Robert Lee Franklin, and Arthur J. Schmucker (employees).

CHARGE: Between 1-5-62 and 1-30-62, *amphetamine sulfate tablets* were dispensed 5 times without a prescription.

PLEA: Guilty by the partnership to 3 counts; by the individuals to 1 count each.

DISPOSITION: 5-17-63. Partnership—\$1,500 fine; Dick—\$1,000 fine; Schmucker—\$500 fine. 7-8-63. Franklin—probation for 2 years.

7324. (F.D.C. No. 48530. S. Nos. 66-061 T, 66-063 T, 66-065/6 T.)

INFORMATION FILED: 4-15-63, Dist. N. Mex., against Kenneth L. Chism, t/a Roswell Truck Stop, Roswell, N. Mex., Albert M. Barnes, and Roy Conn (employees).

CHARGE: Between 7-26-62 and 8-29-62, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty by Chism to 2 counts; by Barnes and Conn to 1 count each.

DISPOSITION: 6-21-63. Chism—1 year in prison suspended and probation for 1 year; Barnes—6 months in prison suspended and probation for 1 year; Conn—6 months in prison suspended and probation for 1 year.

7325. (F.D.C. No. 48909. S. Nos. 37-564 T, 59-881 T, 59-900 T.)

INFORMATION FILED: 7-8-63, N. Dist. Ala., against Claude Smeraglia, t/a East Side Drug Co., Birmingham, Ala.

CHARGE: Between 8-16-62 and 11-27-62, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 7-12-63. \$500 fine.

7326. (F.D.C. No. 48556. S. Nos. 66-085/8 T, 66-090 T.)

INFORMATION FILED: 5-23-63, Dist. N. Mex., against Alton E. Calvert, t/a Roswell Truck Terminal, Roswell, N. Mex., and James A. Northam and Wilson Leon Davis (employees).

CHARGE: Between 8-23-62 and 10-3-62, *amphetamine sulfate tablets* were dispensed 3 times and *dextro-amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty by Calvert and Northam to 2 counts each; by Davis to 1 count.

DISPOSITION: 8-2-63. Calvert—8 months in prison; Northam—6 months in prison; Davis—6 months in prison.

7327. (F.D.C. No. 47862. S. Nos. 27-783/4 T.)

INFORMATION FILED: 9-21-62, Dist. Kans., against Durward L. Sterling, Park City, Kans.

CHARGE: Between 1-19-62 and 2-6-62, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 8-9-63. Sentence of 1 year in prison suspended, and probation for 3 years.

7328. (F.D.C. No. 48194. S. Nos. 20-756/60 T.)

INFORMATION FILED: 4-26-63, W. Dist. Tex., against Eugene Dawson, Waco, Tex.

CHARGE: Between 1-30-62 and 2-6-62, *amphetamine sulfate tablets* were dispensed 5 times without a prescription.

PLEA: Guilty.

DISPOSITION: 8-16-63. Sentence of 3 years in jail suspended, and probation for 3 years.

7329. (F.D.C. No. 48193. S. Nos. 19-631/5 T.)

INFORMATION FILED: 4-26-63, W. Dist. Tex., against Isaac Chamberlain, t/a Chamberlain's Truck Stop, Waco, Tex.

CHARGE: Between 1-15-62 and 1-30-62, *amphetamine sulfate tablets* were dispensed 5 times without a prescription.

PLEA: Guilty.

DISPOSITION: 8-16-63. Sentence of 3 years in jail suspended, and probation for 3 years.

7330. (F.D.C. No. 48516. S. No. 3-210 T.)

INFORMATION FILED: 3-25-63, E. Dist. N.C., against Leo H. McGee, t/a M & M Grill, Raleigh, N.C.

CHARGE: On 2-28-62, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 9-12-63. \$350 fine, and probation for 2 years.

7331. (F.D.C. No. 48534. S. Nos. 77-411/14 T, 77-482/4 T.)

INFORMATION FILED: 7-2-63, M. Dist. N.C., against **James L. McCune, t/a Buck's One Stop Truck Center, Laurinburg, N.C.**

CHARGE: Between 6-21-62 and 6-27-62, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 9-11-63. \$2,000 fine, of which \$1,000 was suspended, 2 years in prison suspended, and probation for 5 years.

7332. (F.D.C. No. 48912. S. Nos. 27-794 T, 28-836 T.)

INFORMATION FILED: 8-23-63, W. Dist. Okla., against **Linden O. Kaiser, Dallas, Tex.**

CHARGE: On 2-16-62 and 9-1-62, *amphetamine sulfate tablets* were dispensed twice without a prescription at Oklahoma City, Okla.

PLEA: Guilty.

DISPOSITION: 9-20-63. Imprisonment for 30 days and probation for 5 years.

7333. (F.D.C. No. 48159. S. Nos. 57-227/34 T.)

INFORMATION FILED: 11-20-62, W. Dist. Okla., against **Richard S. Burns, t/a Burns Drug Store, Canton, Okla.**

CHARGE: Between 3-21-62 and 4-2-62, *dextro-amphetamine sulfate tablets* were dispensed twice, *meprobamate tablets*, *pentobarbital sodium capsules*, *prednisone tablets*, and *Seconal Sodium capsules* were each dispensed once without a prescription, *dextro-amphetamine sulfate capsules* and *Seconal Sodium capsules* were each dispensed once upon requests for prescription refills without obtaining authorization from the prescriber.

PLEA: Guilty.

DISPOSITION: 1-8-63. \$200 fine.

7334. (F.D.C. No. 47883. S. Nos. 40-341/2 T, 40-381/4 T.)

INFORMATION FILED: 10-10-62, S. Dist. N.Y., against **New London Pharmacy, Inc., New York, N.Y., and Martin Solomon and David Feingold (pharmacists).**

CHARGE: Between 9-22-61 and 10-1-61, *dextro-amphetamine sulfate tablets* were dispensed 4 times and *Metadren tablets* were dispensed twice without a prescription.

PLEA: Guilty by the corporation to all counts; by Feingold to 4 counts; not guilty by Solomon.

DISPOSITION: On 11-16-62, the corporation was fined \$1,800; Feingold was fined \$1,000 and given 6 months' suspended sentence of imprisonment.

On 3-15-63, the case against Solomon was tried before the court. The defendant moved for a verdict of acquittal under Rule 29(a) of the Federal Rules of Criminal Procedure on the basis that the United States attorney who had signed the information had been appointed by the district court, and that the statute giving the court such power was unconstitutional. On 4-15-63, the court found the defendant Solomon guilty on two counts and rendered an opinion (216 F. Supp. 835 et seq.) in which the court found both that the defendant had waived the defense by failing to raise a timely objection and, in the alternative, that the statute was constitutional.

On 5-14-63, Solomon was fined \$500, and placed on probation for 6 months.

7335. (F.D.C. No. 48202. S. Nos. 24-462 T, 24-465/6 T.)

INFORMATION FILED: 1-17-63, N. Dist. Ohio, against **Leroy F. Keller and Joseph Moneskey, both of Akron, Ohio.**

CHARGE: Between 1-17-62 and 3-28-62, *dextro-amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty by Keller to 2 counts of the information and not guilty by Moneskey to 3 counts.

DISPOSITION: On 2-1-63, Keller was fined \$250 and placed on probation for 1 year.

On 5-28-63, the case against Moneskey came to trial before the court and jury and was concluded with the return of a verdict of not guilty.

7336. (F.D.C. No. 48188. S. No. 45-741 T.)

INFORMATION FILED: 3-12-63, W. Dist. Mo., against **Carl Smith, Joplin, Mo.**

CHARGE: On 1-17-62, *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury and, on 5-15-63, the jury returned a verdict of guilty. On 5-29-63, the court placed the defendant on probation for 18 months.

7337. (F.D.C. No. 48187. S. No. 45-775 T.)

INFORMATION FILED: 3-12-63, W. Dist. Mo., against **George Siler, Joplin, Mo.**

CHARGE: On 3-27-62, *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury and, on 5-13-63, the jury returned a verdict of guilty. On 5-29-63, the court placed the defendant on probation for 18 months.

7338. (F.D.C. No. 48541. S. No. 35-211 T.)

INFORMATION FILED: 5-28-63, Dist. Minn., against **Lewis Hanson, M.D., Frost, Minn.**

CHARGE: On 2-17-62, *dextro-amphetamine sulfate capsules* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 8-8-63. \$500 fine.

7339. (F.D.C. No. 48906. S. No. 77-481 T.)

INFORMATION FILED: 7-2-63, M. Dist. N.C., against **Ted T. Murray, Fayetteville, N.C.**

CHARGE: 6-20-62, *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 9-9-63. Sentence of 1 year in prison suspended, \$500 fine, and probation for 5 years.

7340. (F.D.C. No. 47126. S. Nos. 3-516/18 R.)

INDICTMENT RETURNED: 8-1-62, S. Dist. W. Va., against **Walter Church, Princeton, W. Va.**

CHARGE: Between 9-29-60 and 12-6-60, *amphetamine hydrochloride tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 8-1-62. Sentence of 1 year in prison.

7341. (F.D.C. No. 47328. S. Nos. 22-611 R, 22-828 R, 24-136 R.)

INFORMATION FILED: 4-18-62, Dist. Kans., against **Willard T. Smith, Kansas City, Kans.**

CHARGE: Between 3-14-61 and 5-16-61, *amphetamine hydrochloride tablets* (counts 1 and 3) were dispensed twice and *amphetamine sulfate tablets* (count 2) were dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: On 3-6-63, the case came on for trial before court and jury. On 3-7-63, the jury rendered a verdict of guilty on counts 2 and 3 and of not guilty on count 1. On 4-5-63, the court sustained a motion for a directed verdict of not guilty on count 2. On 4-5-63, the defendant was sentenced to imprisonment for 1 year on count 3.

7342. (F.D.C. No. 48181. S. Nos. 36-030/4 T.)

INFORMATION FILED: 1-21-63, S. Dist. Miss., against **Scott B. Fedrick (a service station employee), Vicksburg, Miss.**

CHARGE: Between 10-22-61 and 11-27-61, *methamphetamine hydrochloride tablets* were dispensed 5 times without a prescription.

PLEA: Guilty.

DISPOSITION: 5-21-63. \$75 fine, suspended sentence of 9 months in jail, and probation for 9 months.

7343. (F.D.C. No. 47321. S. Nos. 60-221/6 R.)

INFORMATION FILED: 12-12-62, W. Dist. La., against **Green Wall Drug Co., Inc., Shreveport, La., and Claude E. Adams (pharmacist).**

CHARGE: Between 10-29-60 and 4-5-61, *Benzedrine Sulfate tablets* were dispensed 4 times and *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty by Adams to 4 counts; nolo contendere by the corporation to 6 counts.

DISPOSITION: 3-7-63. Adams—\$400 fine. 3-15-63. Corporation—\$300 fine.

7344. (F.D.C. No. 48562. S. Nos. 64-158 T, 64-160 T, 64-359 T, 64-540 T.)

INFORMATION FILED: 6-14-63, E. Dist. S.C., against **Albert Strong Alderman, t/a Alderman Drug Co., Sumter, S.C.**

CHARGE: Between 6-22-62 and 8-6-62, *butabarbital sodium tablets* were dispensed 3 times and *Doriden tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 6-14-63. \$250 fine.

7345. (F.D.C. No. 43722. S. Nos. 2-843 P, 2-859/60 P, 56-595 P, 56-599 P, 56-504 P.)

INFORMATION FILED: 9-23-60, S. Dist. Fla., against **Shea & Prange Pharmacy No. 2 (a partnership), Tampa, Fla., and Harry P. Watkins (pharmacist).**

CHARGE: Between 2-3-59 and 6-2-59, *Dexedrine Sulfate tablets* were dispensed 4 times and *Seconal Sodium capsules* were dispensed twice upon request for

a prescription refill without obtaining authorization by the prescriber.

PLEA: Not guilty.

DISPOSITION: The trial was held before the court and jury from 5-1-63 to 5-3-63. At the termination of the trial, the jury returned a verdict of not guilty.

7346. (F.D.C. No. 48168. S. Nos. 27-697/8 T, 28-433 T, 28-769 T, 29-262/3 T.)

INFORMATION FILED: 11-21-62, S. Dist. Iowa, against Robert B. Findlay and Robert G. Findlay (truck stop employees), Hedrick, Iowa.

CHARGE: Between 11-8-61 and 1-3-62, *desoxyephedrine hydrochloride tablets* were dispensed 4 times and *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty by R. B. Findlay to 4 counts, and by R. G. Findlay to 2 counts.

DISPOSITION: 5-2-63. R. B. Findlay—\$500 fine, plus costs; R. G. Findlay—\$200 fine, plus costs.

7347. (F.D.C. No. 47339. S. Nos. 23-706 R, 88-719 R.)

INFORMATION FILED: 10-10-62, Dist. Kans., against Joseph H. Baker, M.D., La Crosse, Kans.

CHARGE: Between 5-23-61 and 8-4-61, *desoxyephedrine hydrochloride tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 5-27-63. \$1,500 fine, plus costs.

7348. (F.D.C. No. 46690. S. Nos. 21-441/3 R.)

INFORMATION FILED: 8-31-62, N. Dist. Ohio, against Saul Millman, t/a Lexington Drug Co., Cleveland, Ohio.

CHARGE: Between 5-31-60 and 6-3-60, *Equanil tablets* were dispensed twice and *methyltestosterone tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12-13-62. \$3,000 fine and probation for 5 years.

7349. (F.D.C. No. 48185. S. Nos. 57-021/3 T.)

INFORMATION FILED: 3-5-63, S. Dist. Tex., against Herbert R. Oelschlegel, t/a Thrifty Drug No. 1, Corpus Christi, Tex.

CHARGE: Between 2-27-62 and 3-6-62, *glutethimide tablets* and *meprobamate tablets* were each dispensed once without a prescription, and *chlorothiazide tablets* were dispensed once upon request for a prescription refill without authorization from the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 3-25-63. \$1,000 fine, suspended sentence of 2 years in jail, and probation for 5 years.

7350. (F.D.C. No. 48144. S. Nos. 1-08S T, 1-053 T, 1-085 T, 2-074 T, 2-078 T, 2-087 T, 2-089 T, 2-097 T, 64-602 T, 64-608 T.)

INFORMATION FILED: 10-26-62, E. Dist. S.C., against Abram A. Gilmore (pharmacist), Charleston, S.C.

CHARGE: Between 10-19-61 and 3-30-62, *Miltown tablets* were dispensed twice and *Equanil tablets* were dispensed 8 times without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 1-21-63. \$500 fine, 12 months imprisonment suspended, and probation for 3 years.

7351. (F.D.C. No. 48528. S. Nos. 58-121 R, 64-127 T, 64-143 T, 64-159 T, 64-169 T, 64-352 T, 64-357 T, 64-360 T.)

INFORMATION FILED: 6-5-63, E. Dist. S.C., against Iris Drugs, Inc., Sumter, S.C., Marshall C. Hinson (secretary-treasurer), and Maurice A. Blum (pharmacist).

CHARGE: Between 5-17-61 and 9-12-62, *Miltown tablets* were dispensed 7 times and *phenobarbital tablets* were dispensed once without a prescription.

PLEA: Guilty by the corporation to all 8 counts of the information, by Hinson to 5 counts, and by Blum to 3 counts.

DISPOSITION: 6-5-63. Each defendant fined \$250.

7352. (F.D.C. No. 48547. S. Nos. 7-915/17 T, 61-840 T, 62-028 T, 62-344/5 T, 62-347/8 T, 62-350 T.)

INFORMATION FILED: 5-24-63, Dist. Mass., against Belmont Drug, Inc., Worcester, Mass., and Benjamin W. Shack (president and treasurer).

CHARGE: Between 5-11-62 and 8-15-62, *Norodin tablets* were dispensed 3 times, *Equanil tablets* and *Butazolidin tablets* were each dispensed twice, and *Dexedrine Sulfate tablets* were dispensed once upon requests for prescription refills without obtaining authorization by the prescriber and *Premarin tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 6-24-63. Corporation—\$500 fine; Shack—6 months in prison suspended, \$500 fine, and probation for 2 years.

7353. (F.D.C. No. 47354. S. Nos. 62-944 R, 62-950 R, 17-181/2 T, 17-184/5 T.)

INFORMATION FILED: 4-5-63, S. Dist. Ohio, against Elby LaVoyd Raines and Howard Byers (drug store employees), Middleport, Ohio.

CHARGE: Between 7-30-61 and 8-22-61, *penicillin tablets* were dispensed 3 times, *Dexedrine Sulfate tablets* were dispensed twice, and *Syndrox tablets* were dispensed once without a prescription.

PLEA: Guilty by Raines to 2 counts and by Byers to 4 counts.

DISPOSITION: 6-18-63. Raines—\$250 fine and probation for 2 years; Byers—\$300 fine and probation for 3 years.

7354. (F.D.C. No. 47304. S. Nos. 2-354/5 R, 2-858 R, 58-998 R.)

INFORMATION FILED: 8-14-62, N. Dist. Ga., against Julian B. McConnell, t/a McConnell's Pharmacy, Atlanta, Ga., and Wendell Lee Boatright (pharmacist).

CHARGE: Between 1-6-61 and 4-10-61, *Pentids tablets* and *Equanil tablets* were each dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Not guilty by Boatright to 3 counts; nolo contendere by McConnell to 4 counts.

DISPOSITION: The case against Boatright was tried before court and jury on 3-4-63 and 3-5-63. On 3-5-63, the jury found Boatwright guilty on 2 counts and not guilty on one count. On 11-5-62, McConnell was fined \$200 and, on 3-13-63, Boatright was fined \$100.

7355. (F.D.C. No. 48156. S. No. 4-645 T.)

INFORMATION FILED: 11-24-62, W. Dist. Va., against Claude Satterfield, Milton, N.C.

CHARGE: On 3-10-62, *pentobarbital sodium capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2-11-63. Sentence of probation for 3 years.

7356. (F.D.C. No. 47841. S. No. 503 T.)

INFORMATION FILED: 8-27-62, S. Dist. Fla., against Donald Hudnall, St. Petersburg, Fla.

CHARGE: On 11-19-61, *Seconal Sodium capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2-15-63. Sentence of 6 months in prison suspended, \$500 fine, and probation for 3 years.

7357. (F.D.C. No. 48157. S. Nos. 1-695 T, 55-280 T.)

INFORMATION FILED: 11-21-62, M. Dist. Ga., against Charles E. Downs, t/a Silvertown Pharmacy, Thomaston, Ga., and Needham J. Goode (pharmacist).

CHARGE: Between 4-20-62 and 6-21-62, *Seda-symtol capsules* were dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 3-15-63. Downs fined \$500 and Goode fined \$250.

7358. (F.D.C. No. 47346. S. Nos. 62-961/6 R, 17-161/7 T, 17-169 T.)

INFORMATION FILED: 8-21-62, S. Dist. Ohio, against Guy J. Molnar, t/a Owl Rexall Drug Store No. 2, Dayton, Ohio, and Robert H. Neff and Overton C. Moloney (pharmacists).

CHARGE: Between 7-28-61 and 9-13-61, *Syndrox tablets* were dispensed 5 times; *Dexedrine sulfate tablets* and *Miltown tablets* were each dispensed 3 times; *penicillin tablets* were dispensed twice; and *Equanil tablets* were dispensed once without a prescription.

PLEA: Guilty by Molnar to 14 counts; by Neff to 7 counts; by Moloney to 4 counts.

DISPOSITION: 1-9-63. Molnar—\$500 fine; Neff and Moloney—\$250 fine each.

7359. (F.D.C. No. 48160. S. Nos. 70-823/30 T.)

INFORMATION FILED: 11-20-62, W. Dist. Okla., against Cletus S. Long, t/a Canton Drug Store, Canton, Okla.

CHARGE: Between 3-27-62 and 4-2-62, *V-Cillin K tablets*, *pentobarbital sodium capsules*, and *meprobamate tablets* were each dispensed twice and *prednisone tablets* and *dextro-amphetamine sulfate tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 1-8-63. \$200 fine.

7360. (F.D.C. No. 47863. S. Nos. 23-592 R, 27-346/50 T, 27-356/8 T, 27-422 T, 27-722/4 T, 27-730/2 T, 28-413/23 T.)

INFORMATION FILED: 2-18-63, N. Dist. Iowa, against Hartig Drug Co. (a corporation), Dubuque, Iowa, Kenneth A. Hartig (secretary), Don C. Brewer, Alvin R. Luckritz, Richard J. Pauly, and Richard E. Palmer (pharmacists).

CHARGE: Between 7-15-61 and 10-25-61, *Seconal Sodium capsules* were dispensed 8 times, *reserpine tablets* were dispensed 7 times, *Equanil tablets* were dispensed 6 times and *Diuril tablets* were dispensed 5 times, upon requests for prescription refills without obtaining authorization by the prescriber.

PLEA: Nolo contendere by the corporation and Hartig to 26 counts; by Brewer to 9 counts; by Luckritz to 7 counts; by Pauly and Palmer to 3 counts each.

DISPOSITION: 4-19-63. Corporation—\$2,600 fine; Hartig—\$1,300 fine; Brewer—\$450 fine and 1 year in prison both suspended, and probation for 3 years; Luckritz—\$350 fine and 1 year in prison both suspended, and 3 years probation; Pauly—1 year in prison suspended and 2 years probation; and Palmer—1 year in prison suspended and 2 years probation.

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¹ (7321, 7322, 7334-7337, 7341, 7345, 7354) Prosecution contested.

	N.J. No.		N.J. No.
Alderman Drug Co. <i>See</i> Alderman, A.S.		Chamberlain's Truck Stop. <i>See</i> Chamberlain, Isaac.	
Baker, J. H. (M.D.): desoxyephedrine hydrochloride tablets -----	7347	Chism, K. L.: amphetamine sulfate tablets--	7324
Barnes, A. M.: amphetamine sulfate tablets---	7324	Church, Walter: amphetamine hydrochloride tablets -----	7340
Belmont Drug, Inc.: Norodin tablets, Equanil tablets, Butazolidin tablets, Dexedrine Sulfate tablets, and Premarin tablets-----	7352	Cloyds Mountain Truck Stop. <i>See</i> Davidson, O. C.	
Blum, M. A.: Miltown tablets and phenobarbital tablets-----	7351	Conn, Roy: amphetamine sulfate tablets---	7324
Boatright, W. L.: Pentids tablets and Equanil tablets -----	¹ 7354	Crain, W. H.: amphetamine sulfate tablets--	¹ 7321
Bost, J. R.: amphetamine sulfate tablets--	7321	Culp, F. G.: amphetamine sulfate tablets---	7321
Brewer, D. C.: Seconal Sodium capsules, reserpine tablets, Equanil tablets, and Diuril tablets-----	7360	Davidson, O. C.: amphetamine sulfate tablets--	7322
Buck's One Stop Truck Center. <i>See</i> McCune, J. L.		Davis, W. L.: amphetamine sulfate tablets and dextro-amphetamine sulfate tablets-----	7326
Burns, R. S.: dextro-amphetamine sulfate tablets, meprobamate tablets, pentobarbital sodium capsules, prednisone tablets, Seconal Sodium capsules, and dextro-amphetamine sulfate capsules -----	7333	Dawson, Eugene: amphetamine sulfate tablets--	7328
Burns Drug Store. <i>See</i> Burns, R. S.		Dick, G. M.: amphetamine sulfate tablets--	7323
Byers, Howard: penicillin tablets, Dexedrine Sulfate tablets, and Syndrox tablets -----	7353	Downs, C. E.: Seda-symtol capsules-----	7357
Calvert, A. E.: amphetamine sulfate tablets and dextro-amphetamine sulfate tablets-----	7326	East Side Drug Co. <i>See</i> Smeraglia, Claude.	
Canton Drug Store. <i>See</i> Long, C. S.		Fedrick, S. B.: methamphetamine hydrochloride tablets-----	7342
Carter, Mrs. T. I.: amphetamine sulfate tablets---	¹ 7322	Feingold, David.: dextro-amphetamine sulfate tablets and Metandren tablets -----	7334
Chamberlain, Isaac: amphetamine sulfate tablets--	7329	Findlay, R. B.: desoxyephedrine hydrochloride tablets and amphetamine sulfate tablets-----	7346
		Findlay, R. G.: desoxyephedrine hydrochloride tablets and amphetamine sulfate tablets-----	7346
		Franklin, R. L.: amphetamine sulfate tablets--	7323
		Gilmore, A. A.: Miltown tablets and Equanil tablets -----	7350

¹ (7321, 7322, 7334-7337, 7341, 7345, 7354) Prosecution contested.

	N.J. No.		N.J. No.
Goode, N. J. :		McCune, J. L. :	
Seda-symtol capsules_____	7357	amphetamine sulfate tablets__	7331
Green Wall Drug Co., Inc. :		McGee, L. H. :	
Benzedrine Sulfate tablets and		amphetamine sulfate tablets__	7330
amphetamine sulfate tablets_	7343	Millman, Saul :	
Hanson, Lewis, (M.D.) :		Equanil tablets and methyltes-	
dextro-amphetamine sulfate		tosterone tablets_____	7348
capsules _____	7338	Molnar, G. J. :	
Hartig, K. A. :		Syndrox tablets, Dexedrine	
Seconal Sodium capsules, reser-		Sulfate tablets, Miltown tab-	
pine tablets, Equanil tablets,		lets, penicillin tablets, and	
and Diuril tablets_____	7360	Equanil tablets_____	7358
Hartig Drug Co. :		Moloney, O. C. :	
Seconal Sodium capsules, reser-		Syndrox tablets, Dexedrine	
pine tablets, Equanil tablets,		Sulfate tablets, Miltown tab-	
and Diuril tablets_____	7360	lets, penicillin tablets, and	
Hinson, M. C. :		Equanil tablets_____	7358
Miltown tablets and pheno-		Moneskey, Jos. :	
barbital tablets_____	7351	dextro-amphetamine sulfate	
Houser, C. W. :		tablets _____	1 7335
amphetamine sulfate tablets__	7321	Murray, T. T. :	
Hudnall, Donald :		dextro-amphetamine sulfate	
Seconal Sodium capsules_____	7356	tablets _____	7339
Iris Drugs, Inc. :		Neff, R. H. :	
Miltown tablets and pheno-		Syndrox tablets, Dexedrine	
barbital tablets_____	7351	Sulfate tablets, Miltown tab-	
Kaiser, L. O. :		lets, penicillin tablets, and	
amphetamine sulfate tablets__	7332	Equanil tablets_____	7358
Keller, L. F. :		New London Pharmacy, Inc. :	
dextro-amphetamine sulfate		dextro-amphetamine sulfate	
tablets _____	7335	tablets and Metandren tab-	
Lexington Drug Co. :		lets _____	7334
Equanil tablets and methyltes-		Northam, J. A. :	
tosterone tablets_____	7348	amphetamine sulfate tablets	
Long, C. S. :		and dextro-amphetamine sul-	
V-Cillin K tablets, pentobarbi-		fate tablets_____	7326
tal sodium capsules, mepro-		Oelschlegel, H.R. :	
bamate tablets, prednisone		glutethimide tablets, meproba-	
tablets, and dextro-amphet-		mate tablets, and chlorothi-	
amine sulfate tablets_____	7359	azide tablets_____	7349
Luckritz, A. R. :		Owl Rexall Drug Store No. 2 :	
Seconal Sodium capsules, reser-		Syndrox tablets, Dexedrine	
pine tablets, Equanil tablets,		Sulfate tablets, Miltown tab-	
and Diuril tablets_____	7360	lets, penicillin tablets, and	
M & M Grill. <i>See</i> McGee, L. H.		Equanil tablets_____	7358
McConnell, J. B. :		Palmer, R. E. :	
Pentids tablets and Equanil		Seconal Sodium capsules, re-	
tablets _____	7354	serpine tablets, Equanil tab-	
McConnell's Pharmacy. <i>See</i> Mc-		lets, and Diuril tablets_____	7360
Connell, J. B.			

¹(7321, 7322, 7334-7337, 7341, 7345, 7354) Prosecution contested.

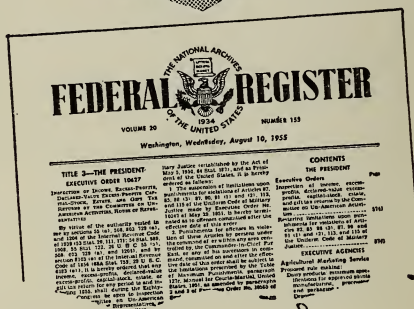
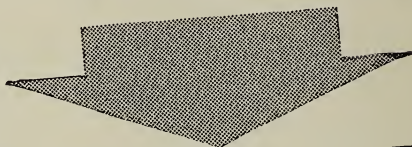
	N.J. No.		N.J. No.
Pauly, R. J.:		Siler, George:	
Seconal Sodium capsules, reserpine tablets, Equanil tablets, and Diuril tablets-----	7360	dextro-amphetamine sulfate tablets -----	¹ 7337
Raines, E. L.:		Silvertown Pharmacy. See	
penicillin tablets, Dexedrine Sulfate tablets, and Syndrox tablets -----	7353	Downs, C. E.	
Richardson, M. C.:		Smeraglia, Claude:	
amphetamine sulfate tablets--	7322	amphetamine sulfate tablets--	7325
Roswell Truck Stop. See Chism, K. L.		Smith, Carl:	
Roswell Truck Terminal. See Calvert, A. E.		dextro-amphetamine sulfate tablets -----	¹ 7336
Sam's Ashland Truck Stop. See Crain, W. H.		Smith, W. T.:	
Satterfield, Claude:		amphetamine hydrochloride tablets and amphetamine sulfate tablets-----	¹ 7341
pentobarbital sodium capsules--	7355	Solomon, Martin:	
Schmucker, A. J.:		dextro-amphetamine sulfate tablets and Metandren tablets -----	¹ 7334
amphetamine sulfate tablets--	7323	Sterline, D. L.:	
Shack, B. W.:		amphetamine sulfate tablets--	7327
Norodin tablets, Equanil tablets, Butazolidin tablets, Dexedrine Sulfate tablets, and Premarin tablets-----	7352	Thrifty Drug No. 1:	
Shea & Prange Pharmacy No. 2:		glutethimide tablets, meprobamate tablets, and chlorothiazide tablets-----	7349
Dexedrine Sulfate tablets and Seconal Sodium capsules----	¹ 7345	Truck Denver:	
		amphetamine sulfate tablets--	7323
		Watkins, H. P.:	
		Dexedrine Sulfate tablets and Seconal Sodium capsules----	¹ 7345

¹(7321, 7322, 7334-7337, 7341, 7345, 7354) Prosecution contested.

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U.S. Department of Health, Education, and Welfare
FOOD AND DRUG ADMINISTRATION

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MAY 22 1964

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD
DRUG, AND COSMETIC ACT

CURRENT SERIAL RECORDS

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

7361-7420

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were alleged to be adulterated or misbranded, or otherwise violative of the Act, when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default, or consent, and including subsequent decrees of dismissal in two cases, the forfeiture of a bond in one case, and the entry of a decree of injunction in another case; (2) criminal proceedings which were terminated upon pleas of guilty and nolo contendere; and (3) injunction proceedings in which a temporary restraining order and other injunction decrees were entered, including, in one case, a summary judgment of permanent injunction. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., April 17, 1964.

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*For omission of, or unsatisfactory, ingredients statements, See Nos. 7362, 7368, 7373, 7380, 7420; an imitation of, and sale under name of, another drug, Nos. 7383, 7407; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 7368, 7380, 7410, 7420; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 7368, 7380, 7420.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D.D.N.J. NOS. 7361-7420

Adulteration, Section 501(a)(2), the article had been prepared and packed under insanitary conditions whereby it may have been rendered injurious to health; Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (National Formulary), and its strength differed from the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents in terms of weight, measure, or numerical count; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient and also including, whether active or not, the name and quantity or proportion of any strychnine contained therein; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; Section 503(b)(1), the article was a drug intended for use by man which because of its toxicity or other potentiality for harmful effect, or the collateral measures necessary to its use, was not safe for use except under the supervision of a practitioner licensed by law to administer such drug, and it was dispensed contrary to the dispensing provisions of this Section; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application, or an approval of an application, filed pursuant to Section 505(b) was not effective with respect to such drug.

**DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED
ACCORDING TO DIRECTIONS****7361. Oral Hydrosulphosol. (Inj. No. 386.)**

COMPLAINT FOR INJUNCTION FILED: 2-3-61, S. Dist. Calif., against E. C. Lientz Sales Co., a corporation, Fillmore, Calif., and Oliver K. Lientz, president, Betty C. Lientz, vice president and secretary, and Elizabeth C. Lientz, treasurer.

NATURE OF DRUG: The *Oral Hydrosulphosol* was intended for internal use in treatment of various diseases of the eye. It consisted essentially of a reddish-orange viscous liquid that contained calcium polysulfides and calcium thiosulfate in a glycerol-water solution, with a total of approximately 10.5 percent sulfur (2.8 percent in the form of thiosulfate sulfur and 7.7 percent in the form of sulfide sulfur and polysulfide sulfur), 4.0 percent calcium, and 66.7 percent glycerol.

NATURE OF BUSINESS: The defendants conducted the interstate distribution of the article as a mail-order business and promoted the business through the use of newspaper and magazine articles and radio and television programs. The defendants sold the article direct to laymen for purposes of self-medication and also promoted sales to doctors, drug wholesalers, and retailers. The article was manufactured by E. C. Lientz & Co., Inc., Fillmore, Calif., a corporation, whose officers were the individual defendants.

LABEL IN PART: (Btl.) "Oral Hydrosulphosol Brand of Calsulphdryl."

ACCOMPANYING LABELING: Reference card entitled "Hydrosulphosol Oral * * * Actions and Uses"; leaflets entitled "In Corneal Scar Treatment Oral Hydrosulphosol," "In Cataract Treatment Oral Hydrosulphosol," and "In Retinal Treatment Oral Hydrosulphosol"; newspaper reprint entitled "Cataracts Yield to Chemicals"; leaflets entitled "Nutritional Therapy in Lens Opacities" and "Case Report Hydrosulphosol In Treatment of Corneal Scars"; reprint of an article entitled "Sulfur Metabolism and Nutrition in the Treatment of Cataract"; leaflet entitled "Sulphydryl Therapy in Ophthalmology: Progress Report"; specimen letter, signed Betty C. Lientz, dated August 25, 1958, and addressed to Robert W. Case.; specimen letter, signed Betty C. Lientz, dated September 24, 1958, and addressed to Robert W. Case.; specimen envelope of E. C. Lientz Sales Co. in which was enclosed letter identified above as specimen letter, signed Betty C. Lientz, dated September 24, 1958, and addressed to Robert W. Case.; specimen letter, signed E. C. Lientz, dated November 18, 1959, and addressed to Virgil Perrill; specimen letter, signed E. C. Lientz, dated October 29, 1959, and addressed to Robert M. DeSalvia; newspaper reprint entitled "Medical Gamble Pays Off: Blind Girl, 11, Attains Sight."

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for the treatment, mitigation, prevention, and cure of corneal scars (opacities), corneal dystrophy, corneal ulcers, cataracts, glaucoma, diabetic retinopathy, iritis, iridocyclitis, vernal catarrh, retinitis proliferans, chorioretinitis, recurrent hemorrhages due to infection, diabetes, or high blood pressure, and other diseases and conditions of the eye that cause impaired vision; 502(f) (1)—the labeling of the article failed to bear adequate directions for use; and 502(j)—the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling.

DISPOSITION: On 5-1-61, the defendants having consented, the court entered a decree of permanent injunction enjoining the defendants against the introduction into interstate commerce, of *Oral Hydrosulphosol* or any similar drug which is misbranded within the meaning of 502(a), 502(f) (1), or 502(j) because it—

(1) Bears or is accompanied by any of the items of labeling specified above or any other written, printed, or graphic matter which represents, suggests, or creates the impression that the drug is adequate or effective for the treatment, mitigation, prevention, or cure of corneal scars (opacities), corneal

dystrophy, corneal ulcers, cataracts, glaucoma, diabetic retinopathy, iritis, iridocyclitis, vernal catarrh, retinitis proliferans, chorioretinitis, recurrent hemorrhages due to infection, diabetes, or high blood pressure, or any other disease of the eye; or

(2) Is consigned to any person who has previously been sent any written, printed, or graphic matter such as is described above; or

(3) Fails in its labeling to bear adequate directions for use in that it is shipped to a layman for self-medication in the treatment, prevention, or cure of diseases of the eye; or

(4) Is dangerous to health in that its labeling suggests prolonged use of the drug in self-medication by the layman in treatment, prevention, or cure of diseases of the eye, or suggests a daily dosage which may cause stomach upset, gastric irritation, or nausea.

It was provided in the decree that the injunction is limited to the extent that it does not apply to the distribution of said drug as a prescription drug, dispensed only on prescription of a physician, on condition that there is strict and full compliance with the requirements of 503(b)(1)(B) and (b)(4), and Regulations §§ 1.3 and 1.106(b), it being understood that the Government as plaintiff does not recognize the drug as therapeutically effective for any purpose, and that the limitation in the scope of the injunction does not constitute approval of any type of distribution of said drug; and

Provided further that for a period not to exceed four months from the date of entry of this consent decree, while defendants are in the process of revising all of their labeling to conform to the terms of this decree, defendants will not be deemed to have violated this decree by reason of shipments of the aforesaid drug to physicians, wholesale drug distributors, or retail pharmacists if all of the following conditions are met:

(1) The labeling of said drug consists solely of the revised label and the revised carton, specimens of which were appended to the decree as an exhibit, which include the statement "Caution: Federal law prohibits dispensing without prescription," and

(2) The defendants give separate written notice to all consignees that this drug is no longer to be considered as an over-the-counter item and that it must be dispensed on prescription only.

Following the entry of the decree various stipulations of the parties were approved by the court from time to time providing for extensions of time for the defendants to revise the labeling of the drug to conform to the terms of the consent decree.

On 6-27-62, the defendants filed a motion to modify the consent decree of permanent injunction and served written interrogatories upon the Government. Answers to the interrogatories were filed on 8-3-61. On 8-21-62, the Government served written interrogatories upon the defendants and thereafter, various extensions of time for the filing of defendants' answers to the interrogatories were stipulated to by the parties. Thereafter, a stipulation was entered into between the defendants and the Government and was approved by the court on 2-4-63, which provided among other things, (1) that the defendants would have an additional period of time, to 4-30-63, within which to revise the labeling of the drug as contemplated by the consent decree; (2) that all proceedings concerning the modification of the consent decree should be removed from the court calendar; (3) that a new drug application for the drug, *Oral Hydrosulphosol*, to be made to the Food and Drug Administration, would not prejudice the rights of the defendants in the action here

involved; (4) that if the new drug application was denied, the defendants should have the option to appeal such decision or to renew their motion for modification of the consent decree; and (5) that the Government was in no way deviating from its position that under the "Drug Amendments of 1962" the drug, *Oral Hydrosulphosol*, was a new drug which must comply with the "new drug" requirements of the law.

7362. Liefcort. (F.D.C. No. 48275. S. No. 39-347 V.)

QUANTITY: 23 btls. at New York, N.Y.

SHIPPED: During August 1962, from Beaurepaire, Quebec, Canada, by Endocrine Research Laboratories.

LABEL IN PART: (Btl.) "Liefcort Adrenocortical Preparation Anabolic 1 cc. equivalent in activity to 50 mg. hydrocortisone Produced by: Endocrine Research Laboratories Beaurepaire, Que., Canada."

RESULTS OF INVESTIGATION: Analysis of the product in other shipments showed that it contained prednisone and estradiol and/or prednisone, estradiol, and testosterone in quantities sufficient to be dangerous to health when used as directed, and that it failed to contain hydrocortisone.

LIBELED: 11-8-62, S. Dist. N.Y.

CHARGE: 501(c)—when shipped, the quality and purity of the article fell below that which it purported or was represented to possess; 502(a)—the label statement "Adrenocortical Preparation Anabolic 1 cc. equivalent in activity to 50 mg. hydrocortisone" was false and misleading since such statement represented and suggested that the article contained hydrocortisone, whereas, the article did not contain hydrocortisone; 502(a)—the label contained representations that there are no known contraindications for use of the article, which representations were false and misleading since there are known contraindications for use of the article; 502(e) (2)—the label failed to bear the common or usual name of each active ingredient; 502(j)—the article was dangerous to health when used in the dosage and frequency recommended and suggested in its labeling; and 505(a)—the article was a new drug which may not be introduced into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drug and it was not exempt from 505 since it did not comply with the regulations promulgated with respect to new drugs for investigational use.

DISPOSITION: 2-15-63. Default—destruction.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION*

7363. Nepco-Gap ampuls. (F.D.C. No. 46985. S. No. 35-411 T.)

QUANTITY: 20 individually ctn'd. vials at Pierre, S. Dak.

SHIPPED: 7-31-61 and 10-10-61, from Taylor, Mich., by New England Pharmacal Co.

LABEL IN PART: (Ctn. and vial) "Nepco-Gap Each 5 Ml. contains 2 Q-Units of Active Enzyme Guanido-Amino-Peptidase * * * Intravenous Only * * * New England Pharmacal Co., Taylor, Michigan."

ACCOMPANYING LABELING: Carton insert in part "Nepco-Gap."

LIBELED: 1-22-62, Dist. S. Dak.

*See also No. 7362.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 11-1-62. Consent—destruction.

7364. Flagyl tablets. (F.D.C. No. 48109. S. Nos. 74-248/9 T.)

QUANTITY: 100 individually ctn'd. btl's., each containing 20 tablets, and 30 individually ctn'd. vials, each containing 10 tablets, at New York, N.Y.

SHIPPED: Prior to 8-15-62, from Le Havre, France, by Pharmacie LeCoeur.

LABEL IN PART: (Ctn.) "Specia Paris Flagyl Metronidazole 20 comprimes doses a 250 milligrammes," "Societe Parisienne d'Expansion Chimique, S.A. * * * 21 Rue Jean, Goujon, Paris (8°)," "20 comprimes doses a 250 mg. d' (hydroxy-2'ethyl)-1 methyl-2nitro-5 imidazole V.389-19634 V.389-P45161," "Made in France Conserver a L'abri de la Lumiere Lot No. 151 P 750"; (ctn. insert) "Flagyl Metronidazole" (written in French); (ctn. and vial) "10 Comprimes Gynecologiques Flagyl (8823 R.P.) 10 comprimes a 0.500 gramme d' (hydroxy-2'ethyl)-1 methyl-2nitro-5 imidazole * * * V.389-19635 V.389-P.45162 Made in France Lot No. 156 T Societe Parisienne d'Expansion Chimique, S.A. Specia 21 Rue Jean, Goujon, Paris (8°)."

LIBELED: 9-24-62, S. Dist. N.Y.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce, since an application filed pursuant to 505(b) was not effective with respect to such drug.

DISPOSITION: 10-26-62. Default—destruction.

7365. Solution Rex Virac. (F.D.C. No. 48052. S. No. 53-338 T.)

QUANTITY: 3 cases, 6 btl's. each, at Seattle, Wash.

SHIPPED: 8-5-62, from Portland, Oreg., by Ruson Laboratories, Inc.

LABEL IN PART: (Btl.) "Solution Rex Virac The Modern Iodine Broad Spectrum Microbicide * * * Active Ingredients: Undecoylium Chloride-iodine 1.80% (Available elemental iodine 0.6%) One U.S. Gallon Ruson Laboratories, Inc., Portland 2, Oregon."

LIBELED: 8-20-62, W. Dist. Wash.; amended libel 8-22-62.

CHARGE: 505(a)—when shipped, the article was a new drug which may not be introduced into interstate commerce, since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 10-18-62. Default—destruction.

7366. Pac-A-Dex timed disintegration capsules, Pacetrol timed disintegration tablets, and dextro-amphetamine sulfate timed disintegration tablets. (F.D.C. No. 47943. S. Nos. 44-533 T, 44-536/8 T.)

QUANTITY: 3 1,000-capsule btl's. of *Pac-A-Dex timed disintegration capsules*; 1 35,000-tablet drum, 3 1,000-tablet btl's., and 1 4,000-tablet btl. of *Pacetrol timed disintegration tablets*; 10 1,000-tablet btl's. of 10-mg. *dextro-amphetamine sulfate timed disintegration tablets*; and 1 20,000-tablet drum, 6 1,000-tablet btl's., and 1 5,000-tablet btl. of 30-mg. *dextro-amphetamine sulfate timed disintegration tablets*, at Philadelphia, Pa., in possession of Pace Pharmacal Co.

SHIPPED: Between 8-22-61 and 12-19-61, from New York, N.Y., and Hoboken, N.J., by Davis-Edwards Pharmacal Corp., and Kingston Laboratories, Ltd.

LABELS IN PART: (Btl.) "Timed Distintegration Capsules Pac-A-Dex Each T.D. Capsule contains: Dextro Amphetamine Sulfate 15 mg. dl-amphetamine Sulfate 15 mg. Butabarbital Sodium 45 mg. * * * Packed and distributed by Pace Pharmacal Co., Philadelphia, Pa."; (drum) "PacetroI TDT Kingston Laboratories, Ltd. * * * Hoboken, N.J."; (btl.) "Timed Distintegration Tablets PacetroI Each T.D. Tablet contains: dl-Amphetamine Sulfate 15 mg. dextro-Amphetamine Sulfate 15 mg. Thyroid 3 gr. Phenobarbital (warning * * *) $\frac{3}{4}$ gr. * * * Packed by Pace Pharmacal Co. Philadelphia, Pa."; (btl.) "Timed Disintegration Capsules dextro Amphetamine Sulfate Each T.D. Cap contains dextro amphetamine sulfate 10 mg. * * * Pace Pharmacal Co., Philadelphia, Pa."; (drum) "Dextro Amphetamine Sulfate 30 Mgs. * * * Timed Disintegration Tablets * * * Kingston Laboratories, Ltd., * * * Hoboken, N.J."; and (btl.) "Timed Disintegration Tablets Dextro Amphetamine Sulfate * * * 30 mg. * * * Pace Pharmacal Co., Philadelphia, Penna."

RESULTS OF INVESTIGATION: The articles in bottles had been repacked by the dealer from bulk stock. The drums were the original containers from one of the shippers. Analysis showed that the 10-mg. *dextro-amphetamine sulfate timed disintegration tablets* contained approximately 75 percent of the declared amount, and that approximately 52 percent of the drug was released in one hour.

LIBELED: 8-14-62, E. Dist. Pa.

CHARGE: *Dextro-amphetamine sulfate timed disintegration tablets* (10-mg.), 501(c)—when shipped and while held for sale, the strength of the article differed from that which it purported to possess; and 502(a)—the label statements (bulk and repack) "Each T.D. Cap contains dextro amphetamine sulfate 10 mg.," (repack) "so prepared that the drug is released over a six to ten hour span," and (bulk) "prepared in a special base to allow the disintegration of the contents throughout a 6-10 hour period in 3 equal releases," were false and misleading as applied to a product which contained less than the declared amount of dextro-amphetamine sulfate, and which did not release this drug at a uniform rate over a six- to ten-hour period.

Pac-A-Dex timed disintegration capsules, dextro-amphetamine sulfate timed disintegration tablets (30 mg.), and *PacetroI timed disintegration tablets*, 505(a)—the articles were new drugs which may not be introduced into interstate commerce, since an application filed pursuant to 505(b) was not effective with respect to such drugs.

DISPOSITION: 11-14-62. Default—destruction.

7367. Decongestion Cold Capsules (timed disintegration). (F.D.C. No. 47599. S. No. 43-600 T.)

QUANTITY: 9 1,000-capsule btls. and 72 100-capsule btls. at Philadelphia, Pa.

SHIPPED: 3-2-62 and 3-6-62, from Jersey City, N.J., by Kingston Laboratories, Ltd.

LABEL IN PART: (Btl.) "Decongestion Cold Capsule Each Capsule Contains: Atropine Sulfate 0.0375 mg., Scopolamine Hydrobromide 0.0219 mg., Hyoscyamine Sulfate 0.1906 mg., Phenylpropanolamine Hydrochloride 50.0 mg., Chlorpheniramine Maleate 4.0 mg., Kingston Laboratories, Ltd., Hoboken, N.J. Dosage: * * * The timed disintegration pellets in each capsule are so timed as to dissolve over a period of several hours releasing their medication slowly to give continuous relief."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 86.2 percent of the declared amount of phenylpropanolamine hydrochloride and approximately 85.5 percent of the declared amount of chlorpheniramine maleate, and, that the capsule disintegrated in one hour.

LIBELED: 5-21-62, E. Dist. Pa.

CHARGE: 501(c)—when shipped and while held for sale, the strength of the article differed from that which it purported to possess; 502(a)—the label statement "Each capsule contains * * * Phenylpropanolamine Hydrochloride 50.0 mg. Chlorpheniramine Maleate 4.0 mg." was false and misleading as applied to a product containing less than the declared amount of these ingredients; 502(a)—the label statement "The timed disintegration pellets in each capsule are so timed as to dissolve over a period of several hours" was false and misleading since it was contrary to fact; and 505(a)—the article was a new drug which may not be introduced into interstate commerce, since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 11-14-62. Default—destruction.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

7368. **Dextro-amphetamine hydrochloride tablets.** (F.D.C. No. 47880. S. Nos. 88-750 R., 27-686 T.)

INFORMATION FILED: 11-8-62, Dist. Kans., against Dan W. Bolton, M.D., Frankfort, Kans.

ALLEGED VIOLATIONS: On 9-22-61, a number of misbranded *dextro-amphetamine hydrochloride tablets* were shipped by the defendant from Kansas to Missouri and, on 7-17-61, while a number of *dextro-amphetamine hydrochloride tablets* were being held for sale, the defendant dispensed such tablets without a prescription.

LABEL IN PART: (Vial) "1 tablet $\frac{1}{2}$ hour before meals for control of appetite Dr. Bolton" and "Tablets for control of appetite; one $\frac{1}{2}$ hour before meals Dr. Bolton."

CHARGE: Shipped tablets: 502(b)—the article failed to bear a label containing (1) the place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents in terms of numerical count; 502(e) (1)—the drug was not designated solely by a name recognized in an official compendium, and it failed to bear a label containing the common or usual name of the drug; 502(f)—the labeling of the drug failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form as were necessary for the protection of users; and 503(b) (4)—the drug was subject to the provisions of 503(b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Dispensed tablets: 503(b) (1)—the dispensing of the tablets without a prescription resulted in the tablets being misbranded while held for sale.

PLEA: Guilty.

DISPOSITION: 2-5-63. 1 year in prison suspended, \$250 fine, plus costs, and probation for 1 year.

7369. **Dextro-amphetamine sulfate capsules and Metandren Linguets.** (F.D.C. No. 47840. S. Nos. 39-441/2 T.)

INFORMATION FILED: 10-24-62, S. Dist. N.Y., against Burnett Maisel, Bronx, N.Y.

SHIPPED: 11-27-61, from New York, N.Y., to Bergenfield, N.J.

CHARGE: 503(b)(1)—when shipped, *dextro-amphetamine sulfate capsules* and *Metandren Linguets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2-6-63. Probation for 6 months.

DRUG IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

7370. Tri-Jan Intervules. (F.D.C. 47587. S. No. 43-599 T.)

QUANTITY: 11,500 capsules in a bulk drum, 12 100-capsule btl., 2 500-capsule btl., and 3 1,000-capsule btl., at Philadelphia, Pa., in possession of Jan Laboratories.

SHIPPED: 1-13-62, from Hoboken, N.J., by Kingston Laboratories, Ltd.

LABEL IN PART: (Drum) "Each Capsule Weighs 7.5 Grains * * * Formula Decongestion Cold Capsules * * * Kingston Laboratories, Ltd. * * * Hoboken, New Jersey * * * Jan Laboratories * * * Philadelphia" and (btl.) "Tri-Jan Intervules Decongestant-Antihistaminic-Anti-secretory. Each capsule contains: Atropine Sulfate 0.0375 mg. Scopolamine hydrobromide 0.0219 mg. Hyoscyamine sulfate 0.196 mg. Total 0.25 mg. Phenylpropanolamine hydrochloride 50.0 mg. Chlorpheniramine maleate 4.0 mg. * * * Jan Laboratories, Phila. Pa."

RESULTS OF INVESTIGATION: Analysis showed that the article contained about 77.8 percent of the declared amount of chlorpheniramine maleate, and about 80 percent of the declared amount of phenylpropanolamine hydrochloride. The article was repacked by the dealer from bulk drums described above.

LIBELED: 5-10-62, E. Dist. Pa.

CHARGE: 501(c)—when shipped and while held for sale, the strength of the article differed from that which it purported to possess; and 503(b)(4)—the article was subject to the provisions of 503(b)(1), and the label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 8-1-62. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS AND DEVICES FOR HUMAN USE**

7371. Amphetamine tablets. (F.D.C. No. 48437. S. Nos. 25/27 V.)

QUANTITY: 6 1,000-tablet btl. at Perry, Ga., in possession of Albert Edward Locke.

SHIPPED: On an unknown date, into the State of Georgia.

LIBELED: 11-30-62, M. Dist. Ga.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use and it was not exempt from such requirement since it was in possession of a person who was not regularly and lawfully engaged in the manufacture, transportation, storage, or distribution of prescrip-

*See also No. 7368.

**See also Nos. 7361, 7368.

tion drugs, and since it was not to be dispensed upon prescription as required by regulations.

DISPOSITION: 2-4-63. Default—delivered to the Food and Drug Administration.

7372. Methamphetamine hydrochloride tablets. (F.D.C. No. 48669. S. No. 45-927 V.)

QUANTITY: 16 5,000-tablet btls. and 13 60-tablet boxes at Donovan, Ill., in possession of Ambrose D. Schneider, M.D.

SHIPPED: Prior to 1-8-63, from outside the State of Illinois.

LIBELED: 1-10-63, E. Dist. Ill.

CHARGE: 502(f) (1)—while held for sale, the labeling of the article failed to bear adequate directions for use and the article was not exempt from such requirement.

DISPOSITION: 2-25-63. Default—destruction.

7373. Verv capsules. (F.D.C. No. 48464. S. No. 45-017 V.)

QUANTITY: 2,372 packets, each containing 2 capsules, at Champaign, Ill.

SHIPPED: 10-22-62, from New York, N.Y., by College Radio Corp.

LABEL IN PART: (Packet) "Verv continuous action alertness capsules—complimentary sample—American Pharmaceutical Company, New York, New York."

LIBELED: 11-28-62, E. Dist. Ill.

CHARGE: 502(e) (1)—when shipped, the label of the article failed to bear the common or usual name of the article; and 502(f) (1)—the labeling failed to bear adequate directions for use for the conditions for which the article was offered.

DISPOSITION: 12-28-62. Default—destruction.

7374. Octogen ointment. (F.D.C. No. 47683. S. No. 11-929 T.)

QUANTITY: 14 70-lb. drums, 11 cases, 12 4-oz. btls. each, 15 cases, 12 2-oz. btls., each, 2 cases, 144 1-oz. btls. each, 60 16-oz. btls., and 6 2-oz. btls., at Utica, N.Y., in possession of Dr. Austin Bender, t/a Octogen Pharmacal Co.

SHIPPED: 2-2-62, from Cleveland, Ohio.

LABEL IN PART: (Btl.) "Octogen For Surface Inflammations and Congestions Net Weight * * * Distributed by Octogen Pharmacal Co. * * * Utica, New York Directions * * * Formula Octogen contains the Essential Oils of Eucalyptus, Pine Needles, Turpentine, Hemlock, Cedar Leaves and Thyme, combined with Methyl-Salicylate and the volatile crystals of Camphor, Menthol."

ACCOMPANYING LABELING: Leaflet in bottle "Octogen (Unguentum) An Every Day Aid for . . ."

RESULTS OF INVESTIGATION: The article was shipped in the bulk drums and was repacked by the dealer into the bottles described above.

LIBELED: On or about 7-2-62, N. Dist. N.Y.

CHARGE: 502(a)—(drums and bottles) while held for sale, the accompanying labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for all external inflammations and congestions, sprains, bruises (unqualified), neuritis, myositis, myalgia, sciatica, lumbago, sacro-iliac conditions, acute and chronic arthritis, rheumatic fever, coryza, croup, laryngitis, tonsillitis, bronchopneumonia, skin diseases,

chronic ulcers, stubborn cases of generalized eczema, athlete's foot, cuts, skin irritation, burns and scalds, and the burning and itching caused by ultra-violet ray treatment; and to enhance markedly the value of infrared actinic ray, and diathermy; and 502(f) (2)—(bottles) the labeling failed to bear the warning statements to the effect that if pain persisted for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age, a physician should be consulted immediately; that the article should not be applied to irritated skin, or if excessive irritation developed; that the user should avoid getting the article into the eyes or on the mucous membranes; and that it should be kept out of the reach of children to avoid accidental poisoning.

DISPOSITION: 2-11-63. Consent—claimed by Dr. Austin Bender and relabeled.

7375. Micro-Dynamometer devices (2 seizure actions). (F.D.C. Nos. 47919/20. S. Nos. 20-860 T; 71-295 T.)

QUANTITY: 2 devices at Duncan and Blackwell, Okla.

SHIPPED: Between 7-1-60 and 6-28-62, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "Manufactured by Ellis Research Laboratories, Inc. Chicago * * * The Ellis Micro-Dynamometer."

RESULTS OF INVESTIGATION: Examination indicated that the devices were essentially galvanometers for measuring electrical currents and electrical potentials of small magnitude. Each device was mounted in a metal cabinet, on the face of which was a scale or meter intended to measure the flow of current in milliamperes, together with a number of dials which could be set at numbered or lettered positions. The dial settings were intended to increase or decrease the resistance to the current flowing through the device. The current which flowed and was measured by the scale or meter, was generated by closing the circuit between two dissimilar metal "probes." The circuit was closed by placing the "probes" at different points on the human body, by placing the "probes" together, or by immersing them in water.

LIBELED: 8-3-62, E. Dist. Okla.; 8-7-62, W. Dist. Okla.

CHARGE: 502(f) (1)—when shipped, the labeling of the articles failed to bear adequate directions for use.

DISPOSITION: 9-19-62; 9-5-62. Default—1 device destroyed; 1 device delivered to the Food and Drug Administration.

7376. Micro-Dynamometer devices (4 seizure actions). (F.D.C. Nos. 47976, 47981, 48013, 48059. S. Nos. 77-790 T; 60-656 T; 66-509 T; 54-116/18 T.)

QUANTITY: 6 devices, at Boonville, N.C., Ironwood, Mich., Boulder, Colo., and Grand Rapids, Muskegon Heights, and Zeeland, Mich.

SHIPPED: Between 11-8-58 and 1-31-62, and on dates unknown, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: (Control panel) "Manufactured by Ellis Research Laboratories Chicago * * * The Ellis Micro-Dynamometer" and (metal plate) "For Scientific Body Analysis The Ellis Micro-Dynamometer."

LIBELED: 8-21-62, M. Dist. N.C.; on or about 8-24-62, W. Dist. Mich.; 9-7-62, Dist. Colo.; 8-24-62, W. Dist. Mich.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for diagnosing disease; and 502(f) (1)—the labeling failed to bear adequate directions for use.

DISPOSITION: 10-11-62; 10-16-62; 11-16-62; 10-9-62. Default—5 devices destroyed; 1 device delivered to the Food and Drug Administration.

7377. Micro-Dynameter devices (4 seizure actions). (F.D.C. Nos. 47986, 48012 48051, 48505. S. Nos. 38-914 T; 5-732 T; 38-425 T; 79-203 T.)

QUANTITY: 4 devices, at Selma, Ala., Waynesboro, Va., Florala, Ala., and Normandy, Mo.

SHIPPED: Between 5-1-51 and 8-11-62, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "For Scientific Body Analysis The Ellis Micro-Dynameter Mfd. by Ellis Research Laboratories, Inc., Chicago, U.S.A."

LIBELED: 8-24-62, S. Dist. Ala.; 9-10-62, W. Dist. Va.; 10-4-62, M. Dist. Ala.; 1-7-63, E. Dist. Mo.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for diagnosing disease; and 502(f) (1)—the labeling of the articles failed to bear adequate directions for use and they were not entitled to any exemption from that requirement.

DISPOSITION: 3-21-63; 9-24-62; 11-6-62; 2-21-63. Default—destruction.

7378. Magnetron device. (F.D.C. No. 47556. S. Nos. 53-073/4 T.)

QUANTITY: 2 devices at Clarkston, Wash.

SHIPPED: 10-17-61 and 1-1-62, from Lewiston, Idaho, by Peter D. Pauls, D.O.

ACCOMPANYING LABELING: Leaflets entitled "Instructions for Using the Magnetron Instrument" and "The New Magnetron."

RESULTS OF INVESTIGATION: The device was a wooden cabinet about 24 inches high by 10½ inches deep by 14¼ inches wide. The control panel was tilted toward the operator and held a large neon "U-shaped" tube, electrode jacks, power switch, intensity control, and fuse holder. The electrodes were a metal cylinder about 1 x 5 inches and a foot pad about 5 x 12 x 1 inches. Main components of the device were a 6,000 volt transformer and two homemade condensers.

LIBELED: 4-25-62, E. Dist. Wash.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective as a treatment for diabetes and tumors, varicose veins, and rheumatoid arthritis; that use of the article would impart new strength, vim, vigor, and vitality to every part of the body which would result in better health; and that use of the article would cause hearts to grow stronger and prostate gland tumors to shrink, build up the blood, improve capillary circulation and nutrition causing local disease symptoms and conditions to disappear; and that the user, through use of the article, might regain and restore health, aid the body to become stronger and healthier, and cause disappearance of disease; and 502(f) (1)—the label failed to bear any directions for use for the conditions for which it was offered, namely, arthritis and rheumatism.

DISPOSITION: 10-19-62. Consent—delivered to the Food and Drug Administration.

7379. Bioelectrometer device. (F.D.C. No. 48279. S. No. 85-642 T.)

QUANTITY: 1 device at San Francisco, Calif., in possession of Kenneth E. Cook, D.C.

SHIPPED: 2-16-62, from St. Louis, Mo.

LABEL IN PART: (Face of device) "Bioelectrometer Electrophysical Resistance Instrument."

ACCOMPANYING LABELING: An instruction manual, a 4-page pamphlet bearing the doctor's name and registration of the device, and a sales promotion-type brochure.

RESULTS OF INVESTIGATION: The device was a metal instrument cabinet containing a power supply and circuitry which provided a voltage between a probe and a hand electrode. The amount of current passing between these two elements was indicated by a microammeter on the instrument control panel.

CHARGE: 502(f) (1)—while held for sale, the labeling failed to bear adequate directions for use in the treatment of the diseases and conditions for which it was intended, namely, arthritis, asthma, bursitis, piles, headaches, constipation, backaches, gas, kidney, heart, or stomach disorders, dizziness, blood pressure, leg pains, migraine, frequent urination, gallbladder pains, and other painful conditions, as represented and suggested in the advertisement reading in part: "Are you Sick of being Sick? Let us apply our scientific New Method of treatment to help correct and relieve your painful condition 'Now' * * *" which appeared in a San Francisco newspaper, dated 8-13-62.

DISPOSITION: 1-3-63. Default—delivered to the Food and Drug Administration.

DRUG FOR VETERINARY USE

7380. Glyoxylide injection. (F.D.C. No. 48439. S. Nos. 22-545 V, 22-617/19 V, 22-625 V.)

QUANTITY: 51 labeled vials, 27 unlabeled 2-cc. vials, 9 labeled 5-cc. vials, and 10 labeled 10-cc. vials, at Brighton, Colo.

SHIPPED: Between 10-12-62 and 11-23-62, from Elsa, Tex., by A. F. de Vore.

LABEL IN PART: (Vial) "R. COOH 12X mfg. for Micro-Nutrients, U.S.A.," "5 cc. 12X Super Gly," and "10 cc. 12X Distemperinum."

ACCOMPANYING LABELING: Leaflets entitled "Glyoxylide-Veterinary Hypodermic Injection for the treatment and control of Acute and Chronic Mastitis, Sterility and other seriously destructive diseases of dairy animals."

LIBELED: 12-28-62, Dist. Colo.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was adequate and effective as a treatment for all seriously destructive diseases of dairy animals, including acute and chronic mastitis and sterility; 502(b)—the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2), on some lots, an accurate statement of the quantity of contents; 502(e) (1)—the label failed to bear the common or usual name of the article; and 502(f)—the labeling failed to bear (1) adequate directions for use and (2) adequate warnings against use.

DISPOSITION: 2-19-63. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF INSANITARY CONDITIONS

7381. *Digitalis* tablets. (F.D.C. No. 48126. S. No. 88-116 T.)

QUANTITY: 17 1,000-tablet btls. at Reidsville, Ga.

SHIPPED: 3-26-62, from Edgewater, N.J., by Excel Pharmacal Co.

LABEL IN PART: "Excel * * * *Digitalis* 1½ Grains Excel Pharmacal Co., Edgewater, N.J."

RESULTS OF INVESTIGATION: Examination showed that the article was contaminated with lindane.

LIBELED: 9-26-62, S. Dist. Ga.

CHARGE: 501(a) (2)—prepared and packed under insanitary conditions whereby it may have been rendered injurious to health.

DISPOSITION: 10-26-62. Default—destruction.

7382. *Thera-30* capsules and phenobarbital-atropine sulfate tablets. (F.D.C. No. 48222. S. Nos. 64-976/7 T, 65-187 T.)

QUANTITY: 56 100-capsule btls. of *Thera-30* capsules and 1 drum, containing approximately 25,000 *phenobarbital-atropine sulfate tablets*, at Lakewood, Calif., and North Hollywood, Calif.

SHIPPED: Between 8-11-61 and 2-14-62, from Long Island City, N.Y., by Nysco Laboratories, Inc.

LABEL IN PART: "*Thera-30*" and "Nysco Laboratories, Inc. Special formula * * * Each Tablet * * * Manufactured by Nysco Laboratories, Inc."

RESULTS OF INVESTIGATION: The *Thera-30* capsules were shipped in bulk containers and were repacked and relabeled by the dealer. Examination showed that both articles were contaminated with lindane.

LIBELED: 10-10-62, S. Dist. Calif.

CHARGE: 501(a) (2)—prepared and packed under insanitary conditions whereby the articles may have been rendered injurious to health.

DISPOSITION: 11-1-62. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICES FOR HUMAN USE*

7383. *Imitation Serpasil* tablets. (F.D.C. No. 47084. S. Nos. 66-801 R, 66-906 R.)

INFORMATION FILED: 6-7-62, W. Dist. Okla., against Elmer L. Phipps, t/a Phipps Drug Co., Oklahoma City, Okla.

ALLEGED VIOLATION: Between 4-26-59 and 4-26-61, while a number of *imitation Serpasil tablets* were being held for sale after shipment in interstate commerce, the defendant caused the drug to be relabeled and offered for sale and sold; and, when the drug was relabeled, and when it was offered for sale and sold, the drug was represented to be *Serpasil* tablets whereas it was not *Serpasil* tablets but was an imitation.

CHARGE: 501(d) (2)—*imitation Serpasil tablets* were substituted for *Serpasil* tablets; 502(a)—the relabeled article had affixed upon its container the false

*See also Nos. 7362, 7366, 7367, 7370.

and misleading representation "Tablets Serpasil * * * CIBA"; 502(i) (2)—the article was an imitation of another drug, Serpasil; and 502(i) (3)—the article was offered for sale under the name of another drug, namely, Serpasil.

PLEA: Nolo contendere.

DISPOSITION: 11-9-62. \$500 fine.

7384. Rutin powder. (F.D.C. No. 47998. S. No. 65-175 T.)

QUANTITY: 1 drum at Gardena, Calif.

SHIPPED: 11-17-61, from New York, N.Y.

LABEL IN PART: "Rutin N.F. powder 25 kilos."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 70 percent rutin, whereas National Formulary requires a minimum of 95 percent.

LIBELED: 8-23-62, S. Dist. Calif.

CHARGE: 501(b)—while held for sale, the article purported to be a drug, the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the standard set forth in such compendium.

DISPOSITION: 9-17-62. Default—destruction.

7385. Hoffman's Super Hi-Proteen tablets, Cookies and Reducing Aid tablets. (F.D.C. No. 45902. S. Nos. 68-231 R, 68-233 R, 68-246 R.)

QUANTITY: 38 pkgs. of cookies, 33 ctns. of tablets, and 4 ctns. of reducing aids, at Tulsa, Okla.

SHIPPED: Between 7-18-60 and 2-20-61, by York Barbell Co., from York, Pa.

LABEL IN PART: (Pkg.) "Contains Hoffman's Super Hi-Proteen 92.6% Protein * * * Hoffman's Hi-Proteen Cookies * * * New Wt. 8 Ounces * * * A 'Muscle Town' Product Made for Bob Hoffman, York Barbell Company * * *"; (ctn.) "Hoffman's Super Hi-Proteen 90 Typical Analysis * * * Protein* .648 gm. per Tablet * * * Made by Bob Hoffman-York Barbell Co. * * * Content 1000 Tablets"; (ctn.) "Hoffman's Hi-Proteen Reducing Aids A New Method of Reducing and Weight Control Plain [or "Chocolate"] Made by Bob Hoffman-York Barbell Co. * * * Contents: 1000 Tablets * * * Anhydrous Protein 31%."

ACCOMPANYING LABELING: Leaflet entitled "How I Reduced"; and books entitled "You Can Live Longer, 10-20-30 Years Longer," "Better Athletes," and "Better Nutrition."

LIBELED: 6-5-61, N. Dist. Okla.

CHARGE: 501(c)—when shipped, the strength of the articles differed from, and their quality fell below, that which they purported to possess, since they contained less than the declared amounts of proteins;

502(a)—misbranded in the label statements "92.6% Protein" (Cookies), "Protein *.648 gm. per Tablet" (*Super Hi-Proteen tablets*), and "Protein 31%" (*Hi-Proteen Reducing Aid tablets-Choc.*), were false and misleading as applied to these products which contained less than the declared amount of protein;

502(a)—the accompanying labeling of the articles contained false and misleading representations that the articles were adequate and effective as a treatment for or preventive of one or more of the following conditions: cancer, diabetes, constipation, shattered nerves, obesity, loss of weight, lowered vitality, gastric and intestinal disturbances, loss of appetite, insomnia, colitis, defective

nutrition in children, secondary anemia, skin diseases, teeth and bone anomalies, falling hair, arthritis, rheumatic diathesis, chronic diseases, vascular lesions of the central nervous system, virus infection, and pneumonia; and to promote longer life, new body tissue, full growth, strength, vigor, regularity, super healthy, energetic people, and athletic physiques;

502(a)—the labeling of the article *Hi-Proteen Cookies*, also contained false and misleading representations that the article was extraordinarily high in protein while being low in calories; and that the American diet was low in protein; that the article would build strong muscles and an athletic physique, rich blood, melt away fat deposits, and normalize the body; and that the article was adequate and effective for reducing and for underweight conditions;

502(a)—(misbranded) the labeling of the article *Super Hi-Proteen tablets*, also contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of scrawny necks, sunken, sagging, wrinkled faces, and to gain strength, energy, and body weight; promote growth in children, strength in hard working individuals, athletes, body builders, and older people, energy, health, healthy tissue, rich red blood, and muscles; and that the article was extraordinarily high in pure protein;

502(a)—the accompanying labeling of the article *Hi-Proteen Reducing Aid tablets*, also contained false and misleading representations that the article was extraordinarily high in protein while low in calories; that the article was concentrated, complete, and well-balanced; that the consumer could live healthfully on the article alone for a month; that the article was an appetite depressant; and that it was adequate and effective for reducing and weight control.

DISPOSITION: 11-8-61. Pursuant to motion by the claimant, and after consideration of the arguments of counsel, the court entered an order directing that the articles be delivered to the claimant under bond for relabeling to show the correct protein content therein, and that following such relabeling, the libel action should be removed to the District of New Jersey for trial on the other issues involved. Thereafter, the articles were inadvertently destroyed by the marshal before delivery was made to the claimant. Accordingly, on 8-15-62, the court entered an order for dismissal of the libel action.

7386. Clinical thermometers. (F.D.C. No. 48098. S. No. 68-367 T.)

QUANTITY: 90 boxes, each containing 12 individually wrapped thermometers, at Chicago, Ill.

SHIPPED: 10-4-61 and 11-17-61, from Ridgewood, N.Y., by Cornell Instrument Co., Inc.

LABEL IN PART: (Envelope) "Tested Clinical Thermometer Kind Stubby Oral Cornell Instrument Company, Inc., Ridgewood, N.Y. Directions For Using Fever Thermometers" and (certificate) "... tested and checked with instruments tested by the National Bureau of Standards."

RESULTS OF INVESTIGATION: Examination of 24 thermometers taken from this consignment showed that 9 thermometers failed to comply with the requirement for accuracy specified by the National Bureau of Standards when tested as described in the standard for clinical thermometers.

LIBELED: 9-10-62, N. Dist. Ill.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported and was represented to possess; and 502(a)—the statement "tested and checked with instruments tested by the National Bureau of

Standards" which appeared in the labeling, namely, the leaflet "Certificate of Examination" was false and misleading since it was contrary to fact.

DISPOSITION: 10-5-62. Default—destruction.

7387. Clinical thermometers. (F.D.C. No. 48099. S. No. 68-365 T.)

QUANTITY: 47 boxes, each containing 36 individually wrapped thermometers, at Lincolnwood, Ill.

SHIPPED: Between 4-6-62 and 6-20-62, from New York, N.Y., by Ipco Hospital Supply Corp.

LABEL IN PART: "IPCO Clinical Thermometer Certificate of Examination The enclosed Fever Thermometer was tested and met or surpassed all the specifications in the U.S. Department of Commerce C.S. 1-52 Commercial Standard for Clinical Thermometers. * * * IPCO Hospital Supply Corporation New York-Chicago-Dallas."

RESULTS OF INVESTIGATION: Examination of 24 thermometers showed 3 thermometers failed to comply with the test for retreating index, 2 of which also failed to comply with the requirement for accuracy as specified by the National Bureau of Standards when tested as described in the standard for thermometers.

LIBELED: 9-10-62, N. Dist. Ill.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported and was represented to possess; and 502(a)—the labeling of the article contained the statement "The enclosed fever thermometer was tested and met or surpassed all the specifications in the U.S. Department of Commerce C.S. 1-52 Commercial Standard for Clinical Thermometers" which was false and misleading since it was contrary to fact.

DISPOSITION: 10-5-62. Default—destruction.

7388. Rubber prophylactics. (F.D.C. No. 47803. S. No. 66-791 T.)

QUANTITY: 98 1-gross ctns. at Detroit, Mich.

SHIPPED: 5-31-62, from Akron, Ohio, by March Rubber & Plastics Co., Inc.

LABEL IN PART: (Ctn.) "In Foil One Gross Three's Poket-Pak Delux Thin Prophylactics March Rubber and Plastics Co., Inc., Akron 6, Ohio * * * Silver Coin Package."

RESULTS OF INVESTIGATION: Examination of 84 prophylactics showed that 3.5 percent contained holes.

LIBELED: 7-18-62, E. Dist. Mich.

CHARGE: 501(c)—when shipped, the quality of the article differed from that which it purported to possess; and 502(a)—the label statement "Sold for Prevention of Disease" was false and misleading as applied to a product containing holes.

DISPOSITION: 9-27-62. Default—destruction.

DRUGS FOR VETERINARY USE

7389. Dyna-Ferm (chick starter premix). (F.D.C. No. 47364. S. No. 85-616 R.)

INFORMATION FILED: 8-24-62, S. Dist. Ind., against Specifide, Inc., Indianapolis, Ind.

SHIPPED: 5-5-61, from Indiana to Kansas.

LABEL IN PART: (Drum) "Specifide DYNA-FERM CS (CHICK STARTER PREMIX) MEDICATED ACTIVE DRUG INGREDIENTS: Arsanilic Acid 1.98% Procaine Penicillin 0.30 gms/lb. NET WEIGHT 100 LBS. P. O. BOX 55263 INDPLS, INDIANA SPECIFIDE, INC. P. O. Box 671 DES MOINES, IOWA."

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than the declared amount of procaine penicillin.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was represented to possess; and 502(a)—the label statement "Procaine Penicillin 0.30 gms/lb." on the drums was false and misleading as applied to an article containing less than 0.30 gms/lb. of procaine penicillin.

PLEA: Guilty.

DISPOSITION: 10-19-62. \$751 fine, plus costs.

7390. Medicated feed. (F.D.C. No. 48094. S. No. 62-125 T.)

QUANTITY: 20 100-lb. bags at Newport, Maine.

SHIPPED: 5-17-62, from Manchester, N.H., by South End Grain, Inc.

LABEL IN PART: "Superior Medicated Potentiated Feed * * * The calcium content of this feed has been reduced to 0.4% to aid in increasing chlortetracycline blood concentrations. Active Drug Ingredient Chlortetracycline HCL (Aureomycin) 0.1 Gm. per lb. (200 Gm. per ton) * * * Dietary Calcium Level 0.4% * * * Ingredients * * * Calcium Sulfate, DiCalcium Phosphate * * * Calcium Pantothenate * * * Caution: Not to be fed continuously for more than 5 days because of lowered calcium content * * * Manufactured by South End Grain, Inc. Manchester, N.H."

RESULTS OF INVESTIGATION: Analysis showed that the article contained an average of 0.016 gm. per lb. of chlortetracycline, and an average of 1.44 percent of calcium.

LIBELED: 9-7-62, Dist. Maine.

CHARGE: 501(c)—when shipped, the quality of the article differed from that which it purported and was represented to possess in that it contained less than the declared amount of chlortetracycline hydrochloride and more than the declared amount of dietary calcium; 502(a)—the label statement "Dietary Calcium Level 0.4%" and "Chlortetracycline HCL (Aureomycin) 0.1 Gm. per lb." were false and misleading since the article contained more than the declared amount of dietary calcium and less than the declared amount of chlortetracycline hydrochloride; and 502(a)—the labeling contained false and misleading representations that the article was a medicated potentiated feed and that it was adequate and effective for increasing chlortetracycline blood concentrations.

DISPOSITION: 10-4-62. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS AND DEVICES FOR HUMAN USE*

7391. Sytobex cyanocobalamin injection. (F.D.C. No. 45398. S. Nos. 21-734 R, 46-518 R.)

QUANTITY: 26 ctn'd. 1-cc. ampuls and 172 ctn'd. 10-cc. vials at Cleveland, Ohio

*See also Nos. 7361, 7362, 7366, 7367, 7374, 7376-7378, 7383, 7385-7389.

SHIPPED: Between 3-9-60 and 12-8-60, from Detroit, Mich., by Parke, Davis & Co.

LABEL IN PART: (Ampul ctn.) "1 CC. size ampoule No. 325 Sytobex Cyanocobalamin Injection"; (vial ctn.) "Sytobex Cyanocobalamin Injection (crystalline vitamin B₁₂ * * * Parke, Davis & Company, Detroit, Michigan"; (vial) "S.V. 96 100 micrograms per cc.," "S.V. 67 30 micrograms per cc.," and "S.V. 119 1000 micrograms per cc."

ACCOMPANYING LABELING: Leaflet in each carton entitled "Sytobex."

LIBELED: 1-25-61, N. Dist. Ohio; amended libel 5-18-62.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was beneficial for the treatment of trigeminal neuralgia, herpes zoster, migraine syndrome, acute porphyria, diabetic and alcoholic neuritis, arteriosclerotic occlusive disease of the lower extremities, and tabes dorsalis.

DISPOSITION: Parke, Davis & Co., appeared as claimant, filed an answer denying that the article was misbranded, and served written interrogatories upon the Government. The Government thereafter filed objections to some of claimant's interrogatories and answers to the others. A motion to amend the misbranding charge set forth in paragraph 3 of the libel was also filed by the Government.

Following this, on 2-21-62, the Government filed written interrogatories to be answered by the claimant. The claimant thereafter filed objections to some of the Government's interrogatories and answered the others. The claimant also filed a motion for a more complete answer to one of its interrogatories. On 5-18-62, the court handed down the following opinion on the motion to amend the libel, claimant's motion for a more complete answer to an interrogatory, and the Government's objections to some of claimant's interrogatories:

KALBFLEISCH, *District Judge*:

1. Application for Leave to Amend

"Libelant's application for leave to amend paragraph 3 of the libel will be sustained upon condition that the proposed new paragraph be incorporated in an amended libel.

2. Motion to Require a More Complete Answer to Interrogatory

"Claimant has moved for an order requiring a more complete answer to its Interrogatory No. 7(a)-7(d) :

With regard to the plaintiff's answer to interrogatory No. 6 above, state with particularity the test or tests, experiment or experiments, analyses, studies, reports, tabulations, papers, references, writings (Provide citations to all medical and scientific publications upon which plaintiff relies.) or other tangible things performed, conducted, used, referred to and/or prepared which serve as the basis for plaintiff's charge that the labeling is 'false and misleading, since [it is] contrary to fact' as to each item listed in paragraphs 6(a) through and including 6(i).

- (a) Describe in detail the method and procedure employed in each such test, experiment, analysis, study or tabulation and the results and indications. Give the date of commencement, the date of termination, and the location and name of clinic, office, laboratory, etc., where each such test or study was conducted.
- (b) Give the name, present address and qualifications of each person who directed, performed and/or conducted each such test, experiment, analysis, study or tabulation.

- (c) Identify all studies, reports, papers, references, charts, records and/or writings by title, date and author and the name and present address of the person having custody of such document or documents.
- (d) Describe each such test as to control subject, test subject, condition of each subject and the severity, duration and origin of each condition or disease.

"Libelant's response to the interrogatory is as follows:

7. Libelant relies on the general consensus of informed scientific opinion in support of its views. Further, libelant knows of no reputable scientific literature which is contrary to or at variance with the views expressed in answer to Interrogatory 6(a)-(i). The only information which libelant has of the research found in the published reports is that contained in those reports. Rather than reply in a manner which would provide little information to claimant, to the effect that libelant is not aware of the details of any such work, the following bibliography, libelant is informed, identifies reports which have been published in this field and which support libelant's views. Some of these reports have been examined by libelant and others have not: * * *. (Following is a list of ten texts and articles.)

"Claimant finds especially objectionable the statement of libelant that it has not examined some of the reports. It asserts that libelant should be ordered to 'specify precisely and fully the medical authorities upon which it relies and which allegedly support its view that the article of drugs under seizure is misbranded.' (Brief, p. 3.)

"In opposing the motion, libelant reasserts that it relies upon 'the general consensus of informed medical opinion in support of its views,' and states that medical experts will testify at trial.

"The Government contends that the product was misbranded in that its labeling states that it is beneficial in the treatment of certain specified diseases when, in fact, it is not. Libelant has stated that it 'performed no tests, experiments, analyses or studies upon the seized article of drug' (Brief, p. 1), being content to accept the statement on the label as to the ingredients.

"If there were no tests or studies made as to this specific drug, of course no reports thereof will be in existence. This leaves only that part of Interrogatory No. 7 which calls for 'studies, reports, tabulations, papers, references, writings' (including medical and scientific publications upon which claimant relies) used or referred to 'as the basis for libelant's charge that the labeling is 'false and misleading * * *'."

"The Court concurs with claimant's position that the libelant should list only those publications with which it is familiar and upon which it intends to rely in support of its position. Otherwise, there is nothing from which it would appear that libelant's answer is not as complete as may be given.

"Libelant will be ordered to reconsider its answer to Interrogatory No. 7 and to delete the names of any works which it has not examined and found to support its position.

3. Objections to Interrogatories

"Libelant objects to certain of claimant's interrogatories. These interrogatories will be considered in order.

Interrogatory No. 1

"State in full the 'labeling' referred to in paragraph 3 of the Libel of Information and indicate (by underlining or other appropriate method) the portion or portions deemed to be misbranded.

"Claimant is seeking information as to precisely what statements of the labeling the Government contends were contrary to fact. It clearly is not a request for production of any specific documents and the objection will be overruled.

Interrogatory No. 3 (b) and (c)

- (b) [State] The names, addresses, job classifications and years of service of each officer, employee and/or agent of the plaintiff who either examined, tested, investigated, read, reviewed, studied, or gave consideration to, in any manner whatsoever, or who has knowledge of relevant facts with regard to the article of drugs under seizure and its labeling, or who participated in making the determination that such drug was misbranded; and
- (c) [State] The part each of the persons listed in answer to the preceding subparagraph took in the examination, investigation and testing of subject article of drugs and its labeling and the determination that such drug was misbranded.

"Libelant objects to the foregoing portions of Interrogatory No. 3 'which seek details other than the name and address of each of libelant's employees who have knowledge of relevant facts, on the ground that the information sought is clearly irrelevant to the subject matter of this case.' (Brief, p. 2.)

"There is no issue as to the analysis of the subject article (Libel of Information, par. 4; Answer, par. 4), the issues being as to the statements on the labels and whether they are false and misleading as alleged by the United States.

"Rule 26(b) defines the scope of discovery procedures, including interrogatories under Rule 33, as 'regarding any matter, not privileged, which is relevant to the subject matter involved in the pending action * * * including * * * the identity and location of persons having knowledge of relevant facts.' Claimant says that libelant, through its employees and agents, has determined that the 'labeling' in issue was misbranded and that the claimant is therefore entitled to inquire as to the qualifications and duties of these employees.

"An analogous question was presented in *General Motors v. California Research Corp.*, 8 F.R.D. 568 (D.C. Del., 1948). There, the defendant, by interrogatory, had requested the names of the corporate officers who had the 'information and belief' that defendant was estopped to assert a certain construction of the patents in issue. The Court sustained objections on the ground of irrelevancy, stating:

The averments of the complaint stated on information and belief are not of substantive independent facts, but of resultant facts formed by an opinion operating on given material. Essentially, the interrogatories ask the names of persons who, having received certain information, are now of the opinion that the specified averments of the complaint are true. * * * The test in this case is whether the names of corporate officers or employees holding certain opinions would be reasonably calculated to lead to the discovery of admissible evidence. I think the names of persons holding certain opinions or beliefs could have no such effect. (Page 570.)

"The claimant has not shown, and this Court is unable to perceive, how the names, job classifications, years of service and parts taken by each of the various government employees and agents in the investigation, processing and filing of this action are relevant to its subject matter or are reasonably calculated to lead to the discovery of admissible evidence. Libelant's objections to Interrogatory No. 3 (b) and (c) will be sustained.

Interrogatory No. 4 (a) through (g)

"State whether plaintiff, or any department, agency, employee, officer or agent thereof, at any time prior to the filing of its Libel of Information herein, prepared any document of any nature whatsoever relating to the article of drugs under seizure and the labeling thereof and/or any other Vitamin B₁₂ preparation which in general has the same therapeutic effects (e.g., salts of Vitamin B₁₂).

- (a) If answer is in the affirmative, identify by title, date and author each study, report, memorandum and/or other writing relating thereto and the name and present address of the person having custody of such documents.

- (b) Does any such document indicate an opinion that the labeling of the article of drugs under seizure might constitute or did in fact constitute a misbranding? Identify each such document by title, date and author.
- (c) With respect to the statement or opinion referred to in the preceding subparagraph (b), explain the facts and identify the medical authorities, texts and other evidence upon which such statement or opinion is based.
- (d) If the answer to the preceding subparagraph (b) is affirmative, state whether or not plaintiff so notified the party in interest prior to January 25, 1961, or took action of any other nature to prevent, or move against, such alleged misbranding. If not, state the reasons why the party in interest was not so notified and no such action was taken.
- (e) Does any document listed in response to subparagraph (a) above indicate an opinion that the labeling of the article of drugs under seizure did not constitute a misbranding? Identify each such document or documents by title, date and author.
- (f) With respect to the statement or opinion referred to in the preceding subparagraph (e), explain the facts and identify the medical authorities, texts and other evidence upon which such statement or opinion is based.
- (g) If the answer to the preceding subparagraph (e) is affirmative, state whether or not plaintiff so notified the party in interest at any time prior to January 25, 1961 of this opinion. If not, state the reason why the plaintiff did not so notify the party in interest.

"By this interrogatory, the claimant calls for a listing and description of every report and memorandum in the Government's files concerning this case or any other case or investigation involving a Vitamin B₁₂ preparation. In addition, claimant asks libelant to identify each such document which contains an expression of opinion as to whether the articles were misbranded, the authorities and an explanation of the facts upon which such opinions were based, and the reasons why the Government did or did not pursue certain courses of action in processing the case.

"The Court is of the opinion that the material requested is irrelevant to the subject matter of this action and is not reasonably calculated to lead to the discovery of admissible evidence. The good faith of the Government and the soundness and scientific accuracy of the internal procedures of its departments and agencies involved in this matter are not at issue here. Claimant is entitled to a list of the medical authorities upon which libelant relies but these are to be furnished pursuant to Interrogatory No. 7.

"Libelant's objections to Interrogatory No. 4 will be sustained.

Interrogatory No. 9 (a) and (b)

"With respect to the article of drugs under seizure, to-wit: Crystalline Vitamin B₁₂ and/or any other Vitamin B₁₂ preparation which in general has the same therapeutic effects (e.g., salts of Vitamin B₁₂)—state any information plaintiff has as to how long such drug has been manufactured in the United States.

- (a) List all persons and manufacturers known to plaintiff, other than Parke, Davis & Company, who have manufactured such Vitamin B₁₂ drug in the United States within the last 15 years.
- (b) If any libel action has been commenced by the plaintiff within the last 15 years against such Vitamin B₁₂ drug manufactured by anyone other than Parke, Davis & Company, identify such action by title, date, court, case number, parties in interest and attorneys for the parties in interest.

"Libelant's objections are on the grounds of irrelevancy, it being contended that no other product except claimant's Sytobex Cyanocobalamin Injection is involved. It would appear that this interrogatory calls for information in the Government's possession relating to similar products. Such material is relevant and appears likely to lead to the discovery of admissible evidence.

"The Court sees no merit in the Government's contention that the furnishing of information concerning the identity of other manufacturers of similar products would be 'unfair' to such manufacturers and to libelant.

"The objections to Interrogatory No. 9 (a) and (b) will be overruled.

"Summarizing, libelant's objections to Interrogatories Nos. 1 and 9 (a) and (b) will be overruled; objections to Interrogatories Nos. 3 (b) and (c) and 4 (a)-(g), inclusive, will be sustained."

On 5-18-62, the court entered an order in accordance with the foregoing opinion. Thereafter, answers to claimant's interrogatories were submitted by the Government. With respect to claimant's objections to the Government's interrogatories, the court handed down the following opinion, on or about 9-4-62:

KALBFLEISCH, District Judge: "This is a civil action *in rem* arising under the provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, et seq. The amended libel alleges that the article preceded against, 'Sytoxex Cyanacobalamin Injection,' is a drug which was misbranded when introduced into and while in interstate commerce within the meaning of 21 U.S.C. 352(a). The libel alleges that the label of the drug in the leaflet entitled 'Sytoxex' contains statements which represent that it is beneficial in the treatment of certain enumerated ailments. These statements are alleged to be false, misleading, and contrary to fact.

"The statements objected to are under the title INDICATIONS and read as follows:

Patients with various other conditions have been reported to have received benefit, usually relief of pain, following administration of vitamin B₁₂ in high dosage. While the indications for such use are not established yet, there have been favorable reports of employment in such conditions as trigeminal neuralgia, posteriolateral sclerosis, herpes zoster, migraine syndrome, acute porphyria, diabetic and alcoholic neuritis, arteriosclerotic occlusive disease of the lower extremities, tabes dorsalis, and subacute combined sclerosis.

"The United States Marshal for this District seized the drugs on January 26, 1961. Thereafter, Parke, Davis & Company, of Detroit, Michigan, intervened and filed claim to them.

"Libelant has propounded 43 interrogatories to the claimant. Claimant has objected to those numbered 25, 33, 38 and 43.

"In objection to interrogatory No. 25, the claimant has said that it does not know the answer to the interrogatory. Libelant has accepted that statement as an answer; therefore, interrogatory No. 25 need not be answered further.

"Libelant has acquiesced in claimant's objection to interrogatory No. 38; therefore, that interrogatory need not be answered by claimant.

"The 33rd interrogatory reads as follows:

State in detail:

- (a) The name and address of all persons who communicated with claimant in any manner whatsoever their satisfaction with Sytoxex.
- (b) The substance of each such communication referred to in (a).
- (c) The date of each communication referred to in (a).
- (d) Specify whether each communication referred to in (a) is oral or written.
- (e) The name and address of each person who has custody of each written communication.
- (f) The address at which each written communication may be examined.

"Claimant objects that the information sought in this interrogatory is immaterial, irrelevant and oppressive, in that it seeks information concerning communications to the claimant about uses of the drug which are not in question in this case.

"It appears that the drug has some recognized uses in the treatment of certain diseases, for which its effectiveness is not questioned. In claimant's brief these are listed as pernicious anemia, nutritional macrocytic anemia, tropical and non-tropical sprue, and megaloblastic anemia of infancy. Libelant has not contested this classification, nor does libelant deny that the drug may be effective in the treatment of posteriolateral sclerosis and subacute combined sclerosis. Statements made by third parties to the claimant concerning the drug's beneficial results in the treatment of these seven diseases do not appear relevant to the current controversy; and it is understood that production of such statements might involve much effort and considerable expense. See IV, Moore's Federal Practice, paragraph 33.20.

"However, from the statements in the leaflet which caused the instigation of this seizure, it may be possible to draw an inference that there have been reports that the drug is beneficial in the treatment of diseases in addition to those for which it is an accepted treatment, and other than those enumerated in the leaflet. If this is so, the libelant is entitled to know of such findings and to have the information necessary to evaluate them. Such communications conceivably can be relevant to the controversy in this action, and may lead to the discovery of admissible evidence. Rules 26(b) and 33, Federal Rules of Civil Procedure.

"Therefore, the claimant will answer the libelant's 33rd interrogatory as if the introduction and subdivision (a) thereof read:

State in detail:

(a) The name and address of all persons who communicated with claimant in any manner whatsoever their satisfaction with the uses of Sytobex other than as a treatment for pernicious anemia, nutritional macrocytic anemia, tropical and non-tropical sprue, megaloblastic anemia of infancy, posteriolateral sclerosis and subacute combined sclerosis.

It will be so ordered.

Interrogatory No. 43 is as follows:

In the event claimant hereafter conducts or has conducted on its behalf or for its use or becomes aware of any test or study pertaining to the information requested in Interrogatory 39 and/or Interrogatory 41, then furnish in detail with respect to each such test or study all the data called for by Interrogatory 40 when such data becomes available to claimant.

"In effect, libelant has asked for the detailed results of any further tests or studies of the drug which may be conducted for claimant, or which may come to claimant's knowledge.

"Claimant objects that by the broad scope of this interrogatory it would be compelled to furnish libelant with any information which claimant may gather from general scientific publications, in addition to that which it may acquire from its own research. It says that such information is as available to the libelant as it is to the claimant. Claimant further contends that the interrogatory seeks to compel it to furnish libelant with the results of tests conducted at the request of claimant's attorneys in their preparation for trial.

"Results of further tests or studies of the drug by claimant clearly will not be the work product of the claimant's attorney within the rule of *Hickman v. Taylor*, 329 U.S. 495, and may be relevant to this case. However, it does appear that because the interrogatory contains the phrase 'or becomes aware of,' strict enforcement of it would require claimant to furnish libelant with all information concerning this drug that claimant might obtain from general sources of scientific information, in addition to the information it acquires from its own research. To force claimant to divulge to libelant information obtained, for instance, from medical journals, would in fact be to force claimant to do libelant's research for libelant. There appears to be no justification for such a requirement. Libelant can be presumed to have at least as sufficient facilities for obtaining such information as has the claimant. Under these circumstances, enforcement of the interrogatory as propounded would not be a proper

use of the discovery rules. See 7 *Cyclopedia of Federal Practice*, Section 25.451, and the cases cited therein.

"Therefore, claimant will answer the interrogatory as if it read :

In the event claimant hereafter conducts or has conducted on its behalf, or for its use, any test or study pertaining to the information requested in Interrogatory 39 and/or Interrogatory 41, then furnish in detail with respect to each such test or study all the data called for by Interrogatory 40 when such data become available to the claimant.

It will be so ordered."

Pursuant to the above opinion, the court entered an order, on 9-4-62, directing the claimant to answer the Government's interrogatories Nos. 33 and 43 as restated by the court. On 3-22-63, the following consent decree of condemnation and injunction was entered :

KALBELEISCH, *District Judge*: "On January 25, 1961, a Libel of Information against the above described article was filed in this Court. The Libel prays condemnation of the article and alleges that the article is a drug which was shipped in interstate commerce and which was misbranded when introduced into and while in interstate commerce, within the meaning of 21 U.S.C. 352(a). Pursuant to monition issued by this Court, the United States Marshal for this District seized said article. Thereafter, Parke, Davis and Company, a Michigan corporation, intervened and filed claim to the article.

"The labeling involved in this case, namely, the leaflet entitled, 'Sytoxex,' was devised by claimant in the good faith belief that the representations of therapeutic effect were true and not misleading, were appropriately qualified, and were in full conformance with the applicable provisions of the Federal Food, Drug and Cosmetic Act. However, recognizing the merits of libellant's position in the light of the exigencies of policing the Federal Food, Drug and Cosmetic Act, claimant consents that a decree of condemnation as prayed for in the Libel be entered against the article under seizure without any adjudication as to any issue of fact or law and without any admission as to misbranding.

"The claimant states that on its own volition it amended the labeling involved in this case prior to the institution of this action and claims no intention of resuming the use of the former labeling. Claimant further consents that a decree of permanent injunction be entered against it, prohibiting it and its officers, agents, servants, employees and representatives and all persons in active concert or participation with them or any of them from introducing or causing to be introduced or delivering or causing to be delivered for introduction into interstate commerce the drug known as 'Sytoxex Cyanocobalamin Injection' under the labeling claims referred to in paragraph 3 of the Libel of Information, as amended, unless and until an approval of an application filed pursuant to Section 505(a) of the Federal Food, Drug and Cosmetic Act (21 U.S.C.A. 355(a)) is effective with respect thereto.

"Upon the foregoing considerations and the Court being fully advised in the premises, it is on motion of the parties hereto, -

"ORDERED, ADJUDGED, AND DECREED that the said article under seizure is hereby condemned pursuant to 21 U.S.C. 334(a); and it is further

"ORDERED, ADJUDGED, AND DECREED that the United States Marshal for this District shall forthwith destroy the seized article and the seized leaflets entitled, 'Sytoxex,' and make return to this Court; and it is further

"ORDERED, ADJUDGED, AND DECREED pursuant to 21 U.S.C. 334(e) that the United States of America shall recover from the said claimant court costs and fees, and storage and other proper expenses, to be taxed; and it is further

"ORDERED, ADJUDGED, AND DECREED that claimant, its officers, agents, servants, employees, and representatives and all persons in active concert or participation with them or any of them, are hereby permanently enjoined from introducing or causing to be introduced, or delivering or causing to be delivered for introduction into interstate commerce, the drug, 'Sytoxex Cyanocobalamin Injection,' or the same drug by any other designation under

the labeling claims referred to in paragraph 3 of the Label of Information, as amended, unless and until an approval of an application filed pursuant to Section 505(a) of the Federal Food, Drug and Cosmetic Act (21 U.S.C.A. 355 (a)), is effective with respect thereto."

7392. Cyanocobalamin injection. (F.D.C. No. 48435. S. Nos. 9-368/72 V.)

QUANTITY: 20 cases, 10 30-cc. vials each, 1 case containing 50 30-cc. vials, 1 case containing 23 30-cc. vials, and 8 cases, 10 10-cc. vials each, at Newark, N.Y.

SHIPPED: Between 7-10-62 and 11-6-62, from Philadelphia, Pa., by Richlyn Laboratories.

LABEL IN PART: (Vial) "Cyanocobalamin Injection U.S.P. Vitamin B₁₂ Crystalline 1,000 [or "100"] MCGM. Per cc. Distributed by Wayne Drug Co., Inc., Newark, N.Y. Dosage * * * Caution * * * Each cc. contains * * * For Intramuscular, Intravenous, or Subcutaneous Injection."

ACCOMPANYING LABELING: Carton insert entitled "Cyanocobalamin U.S.P. (Vitamin B₁₂)."

LIBELED: 12-27-62, W. Dist. N.Y.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was adequate and effective as a treatment for sensory neuropathies, trigeminal neuralgia (tic douloureux), secondary burning paresthesia, diabetic neuritis, alcoholic neuritis, other neuritides where pain is a major component, herpes zoster, and neuroblastoma in children.

DISPOSITION: 2-18-63. Default—destruction.

7393. Crysto-Vim 12 injection. (F.D.C. No. 47716. S. No. 58-754 T.)

QUANTITY: 82 vials (100 micrograms) and 148 vials (1,000 micrograms) at Wichita, Kans., in possession of Archer-Taylor Drug Co.

SHIPPED: 4-20-62, from Detroit, Mich.

LABEL IN PART: (Vial and ctn.) "Parenteral 10 cc Vial Crysto-Vim 12 * * * For Intramuscular Use Only Each cc contains 100 [or "1000"] Micrograms Crystalline Vitamin B₁₂ U.S.P. in Isotonic Solution of Sodium Chloride * * * Archer-Taylor Co. Distributors Wichita Kansas."

ACCOMPANYING LABELING: Carton insert entitled "Solution Crysto-Vim 12 (Brand of Crystalline B₁₂) Archer-Taylor Co."

RESULTS OF INVESTIGATION: The article was shipped in unlabeled vials and thereafter labeled by the dealer as above.

LIBELED: 7-25-62, Dist. Kans.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was adequate and effective for the treatment of trigeminal neuritis (tic douloureux), peripheral neuritis, diabetic neuritis, herpes zoster, postherpetic neuralgia, tabetic crisis, neuritides in general when pain is a major component, pain associated with occlusive vascular disorders, traumatic neuritis, sphenopalatine neuralgia, lumbar segmental neuritis, diphtheritic neuritis, radiculitis, and neuritis of the extremities.

DISPOSITION: 12-27-62. Consent—claimed by Archer-Taylor Drug Co. and relabeled.

7394. Amovit tablets. (F.D.C. No. 48226. S. No. 83-723 T.)

QUANTITY: 18 100-tablet btl. and 12 1,000-tablet btl., at Kirksville, Mo., in possession of Harper Laboratories, Inc.

SHIPPED: 1-16-62, from Chicago, Ill.

LABEL IN PART: (Btl.) "Amovit Each Tablet Contains: Methionine 100 Mgs. Panthenol 2 Mgs. Inositol 50 Mgs. Niacinamide 20 Mgs. Thiamine HCL 3 Mgs. Ascorbic Acid 25 Mgs. Riboflavin 2 Mgs. Pyridoxine 1 Mg. Choline Bitartrate 50 Mgs. Dosage 3 to 6 tablets daily * * * Caution: Federal law prohibits dispensing without a prescription Mfd. for Harper Laboratories, Inc., Kirksville, Mo."

ACCOMPANYING LABELING: Leaflets entitled "Amovit" and additional repack labels.

RESULTS OF INVESTIGATION: The article was shipped in bulk and repacked by the dealer, who also had the leaflets printed for the purpose of promoting sales of the product.

LIBELED: 10-31-62, E. Dist. Mo.

CHARGE: 502(a)—while held for sale, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective as a treatment for chronic fatigue, diabetes, arteriosclerosis, obesity, pregnancy, degenerative diseases, cirrhosis, pancreatitis, alcoholism, psoriasis, hepatic insufficiency, hypothyroidism, and B-complex deficiencies.

DISPOSITION: 12-14-62. Default—destruction.

7395. Dried liver tablets and vitamin tablets and capsules. F.D.C. No. 47129. S. Nos. 43-385/6 T, 43-388/9 T.)

QUANTITY: 396 btl. of *dried liver tablets*, 372 btl. of *vitamin E capsules*, 205 btl. of *vitamin A capsules*, and 270 btl. of *multiple vitamins tablets*, at Penns Creek, Pa., in possession of Walnut Acres. Each lot consisted of 125-, 250-, 500-, and 1,000-tablet or capsule btl.

SHIPPED: On various dates between 12-20-60 and 12-20-61, from Jersey City, N.J., New York, N.Y., and South Hackensack, N.J.

LABEL IN PART: (Btl.) "Natural Dried Liver Tablets [or "Natural Vitamin E-100 I. U. Perles" or "Natural Vitamin A-25,000 U.S.P. Units Perles" or "Natural Multiple Vitamins—One-A-Day Tablets"] Walnut Acres Natural Foods—Natural Farming * * * A Food Supplement For Dietary Purposes Only Manufactured for Walnut Acres, Penns Creek, Pa."

ACCOMPANYING LABELING: Price lists entitled "Walnut Acres—Natural Foods, Natural Farming."

RESULTS OF INVESTIGATION: The price lists were printed on order of the dealer and were used to promote sales of the articles listed therein by mailing to customers and shipping with orders.

LIBELED: 2-9-62, M. Dist. Pa.

CHARGE: 502(a)—while held for sale, the labeling accompanying the articles contained false and misleading representations that the articles were adequate and effective for the treatment and prevention of (*dried liver tablets*) eye degeneration, anemia, nervousness, digestive upsets, insomnia, eczema and skin disorders; and to promote appetite and growth; (*vitamin E capsules*) problems associated with the menopause and aging generally; loss of sexual and general vigor; sterility; muscular and cardiovascular difficulties; and for

normal growth; (*vitamin A capsules*) colds, skin blemishes, lowered vitality, and to resist infections; keep eyes and skin healthy; develop sound bones and teeth; delay senility; and increase life span; and (*multiple vitamins tablets*) colds, sinus infection, allergies, anemia, insomnia, mental depression, eye degeneration, and skin eruption; to resist infections; and promote appetite and growth.

DISPOSITION: 10-17-62. Consent—claimed by Paul Keene, t/a Walnut Acres. The articles were released under bond and the labeling was destroyed.

7396. Vitamin B₁ tablets and niacin tablets. (F.D.C. No. 47438. S. Nos. 25-184/5 T.)

QUANTITY: 1 25,000-tablet drum, 1 11,000-tablet drum, and 17 100-tablet btls. of vitamin B₁ and 1 49,900-tablet drum and 93 100-tablet btls. of niacin, at Detroit, Mich., in possession of The Hartz Co.

SHIPPED: 11-4-61 and 12-19-61, from Philadelphia, Pa., and Long Island City, N.Y.

LABEL IN PART: (Drum) "Thiamin Chloride Tablets 100 mg. Each tablet contains (33,300 U.S.P. Units) * * * Crystalline Vitamin B₁ * * * Dec. 26 1961"; (btl.) "100 Tablets Vitamin B₁ (Thiamine Hydrochloride) 100 mg. * * * Manufactured for The Hartz Company * * * Detroit, Mich."; (drum) "Niacin * * * 100 mg."; and (btl.) "100 Tablets Nicotinic Acid (Niacin) 100 mg. Manufactured for The Hartz Company."

ACCOMPANYING LABELING: Pamphlets entitled "What You Should Know About Vitamins For better, healthier Living."

RESULT OF INVESTIGATION: The articles were repacked by the dealer into the bottles from the bulk lots described above.

LIBELED: 4-12-62, E. Dist. Mich.

CHARGE: 502(a)—while held for sale, the labeling accompanying the article contained false and misleading representations that the article (*vitamin B₁ tablets*) was adequate and effective for the treatment and prevention of improper nerve function, peripheral neuritis, and cardiac disease; and to promote growth and health, cardiovascular function, and appetite; and that the article (nicotinic acid (*niacin*) *tablets*) was adequate and effective for the treatment and prevention of dermatitis, glossitis, gastrointestinal disturbance, nervous system disfunction, angina pectoris, and thrombophlebitis; and for the promotion of health, tissue respiration, growth, gastrointestinal function, and normal skin.

DISPOSITION: On 5-8-62, The Hartz Co., claimant, filed an answer denying that the articles were misbranded. Thereafter, on 7-26-62, claimant having consented, the court entered a decree of condemnation and the articles were released under bond for relabeling.

7397. Nutri-Bio food supplements. (F.D.C. No. 47671. S. Nos. 52-785/6 T.)

QUANTITY: 15 ctns., each containing 6 pkgs. of 26 envelopes of vitamin and mineral tablets, and 13 ctns., each containing 8 envelopes of protein (meatless) tablets, at Corvallis, Oreg., in possession of Mrs. Penny Hostetter.

SHIPPED: 6-12-61, from Beverly Hills, Calif., by Nutri-Bio Corp.

LABEL IN PART: (Ctn.) "Nutri-Bio dietary food supplement natural or organic Vitamins and Minerals 365 Mineral Tablets 182 Vitamin Tablets Formulated for and Distributed by Nutri-Bio Corporation, 291 S. La Cienega Blvd. Beverly Hills, California." and (ctn.) "Nutri-Bio food supplement Protein

(meatless) * * * in Ready-T-Eat Tasty Concentrated Tablets 360 Tablets Formulated for and Distributed by Nutri-Bio Corporation, 291 S. La Cienega Blvd., Beverly Hills, California."

ACCOMPANYING LABELING: Nutri-Bio Sales Manuals; reprints of San Jose State College Track Coach/Nutri-Bio letter July 31, 1958, Great Falls Electric letter with enclosure June 25, 1958, Rex Johnston/Nutri-Bio letter August 9, 1958, San Jose State College Boxing Coach/Nutri-Bio letter July 31, 1958, "More Athletes on Nutri-Bio," "Southern Association Vitamins Help," and 1957 issue of "Specialty Salesman"; pamphlets entitled "For More Radiant Living," "Why A Food Supplement," "Nutri-Bio Program For Better Living," and "Do You Know"; leaflets entitled "Basic Philosophy Of Good Nutrition"; letters addressed "Dear Friend"; and books entitled "Let's Eat Right To Keep Fit."

LIBELED: 6-19-62, Dist. Oreg.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for the treatment and prevention of loss of appetite, constipation, hemorrhage of mucous membrane, palpitation of the heart, nervousness, excessive bleeding, rundown feeling, toxic elements in the digestive system, polio, allergies, mumps, colds, colitis, corneal ulcers, boils, carbuncles, muscular dystrophy, eye infections, intestinal hemorrhages, diarrhea, loss of sex potency, heart disease, alcoholism, rheumatism, hay fever, infectious diseases, degenerative conditions, cancer, poor digestion, and fatigue; to promote resistance to infection, stamina and endurance, quicker reflexes, mental alertness, strength, growth, radiant living, general well-being, athletic ability, added energy, and increased physical endurance; and to restore black hair which has turned gray, vim, vitality, vigor, health and well-being, and zestful living; to obtain and maintain normal body weight; and that the articles were of significant value for special dietary supplementation and therapeutic use because the ingredients of the articles were of natural or organic origin; because the vitamin and mineral tablets contained unsaturated fatty acids, inositol, para-aminobenzoic acid, rutin, biotin, bioflavonoid complex, hesperidin complex, alfalfa juice and powder concentrate, potassium, sulfur, choline, copper, zinc, manganese, magnesium, montmorillonite, and other nutritive factors and trace elements; and because the protein (meatless) tablets were a source of protein.

DISPOSITION: 9-5-62. Default—destruction.

7398. Blackstrap molasses tablets. (F.D.C. No. 48282. S. No. 33-642 V.)

QUANTITY: 71 150-tablet btl. and 54 300-tablet btl. at Minneapolis, Minn.

SHIPPED: 6-18-62 and 9-10-62, from Newark, N.J., by Plantation Foods, Inc.

LABEL IN PART: "Plantation 'The Original' Brand Blackstrap Molasses Vi-Tabs

* * * Dehydrated Blackstrap Molasses Distributed by Plantation Foods, Inc.

Newark, New Jersey * * * A rich natural source of vitamins and minerals."

LIBELED: 11-8-62, Dist. Minn.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was adequate and effective for the prevention and treatment of nutritional anemia; to promote buoyant health and good appetite, strong bones and teeth, and steady nerves; to build red blood; and that the article was of significant value for special dietary supplementation and

therapeutic use by reason of the presence therein of iron, calcium, vitamin B₁, and other vitamins.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 1-4-63. Default—destruction.

7399. Safflower oil capsules. (F.D.C. No. 47583. S. No. 63-313 T.)

QUANTITY: 21 100-capsule btl. of safflower oil with vitamin B₆, at Bloomington, Minn., in possession of Gem, Inc.

SHIPPED: 3-6-62, from Detroit, Mich.

LABEL IN PART: "Safflower Oil with Vitamin B-6 Distributor Professional Dietary Quotas Company St. Paul, Minnesota."

ACCOMPANYING LABELING: Books entitled "Calories Don't Count" by Herman Taller, M.D.

RESULTS OF INVESTIGATION: The article had been shipped in bulk as described above and, thereafter, was repacked into the bottles by Vitamin Council, Inc., St. Paul, Minn.

The above-mentioned books were placed on display with the articles in the drug department of Gem, Inc.

LIBELED: 5-8-62, Dist. Minn.

CHARGE: 502(a)—while held for sale, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective for the control of body weight and to reduce and to maintain slimness, even though consuming many thousands of calories daily without regard to the total caloric intake; to lower and control the cholesterol level of the blood; for the treatment and prevention of arteriosclerosis, heart disease, diabetes, and heartburn; to improve the complexion; increase resistance to colds and sinus trouble; promote health; and increase sexual drive; and the label of the article, while held for sale, contained false and misleading representations that the article was of significant value for special dietary supplementation by reason of the presence therein of safflower oil.

DISPOSITION: 6-22-62. Default—the article was destroyed and the accompanying books were delivered to the Food and Drug Administration.

7400. Safflower oil products. (F.D.C. No. 47662. E. Nos. 53-521/2 T, 53-524/5 T.)

QUANTITY: 2 500-capsule btl., 97 250-capsule btl., 175 100-capsule btl., and 6 5,000-capsule drums, of *safflower oil perles*; 58 1-gal. btl., 314 1-qt. btl., 313 1-pt. btl., 88 ½-pt. btl., and 96 55-gal. drums, of *safflower seed oil*, 51 1-lb. pkgs., and 17 cases, each containing 30 1-lb. pkgs., of *safflower all vegetable spread*; and 88 12-oz. pkgs., and 11 cases, each containing 30 12-oz. ctns. of *vegetable margarine*, at Portland, Oreg., in possession of Healthway Food Center.

SHIPPED: Capsules: 3-26-62 and 4-3-62, from South Pasadena, Calif., by Banner Gelatin Products Corp. Oil: 2-20-62 and 3-26-62, from Berkeley, Calif., by Pacific Vegetable Oil Corp. Spread: 3-16-62 and 4-20-62, from Los Angeles, Calif., by Kahan & Lessin Co. Margarine: 2-16-62, from Los Alamitos, Calif., by Sona Food Products, Inc.

LABEL IN PART: (Btl.) "Healthway's Safflower Oil Perles With B-6 * * * Distributed by Healthways Food Center"; (drum) "Capsules Safflower Oil+

Vit. B₆ Edible Safflower Oil 1100 to 1150 Mg. Vitamin B₆ * * * 3 Mg. A Dietary Supplement Quantity 5000 * * * Banner Gelatin Prods. Corp. * * * South Pasadena, Calif."; (btl.) "Healthway's Cold Pressed Saf-Flower Seed Oil * * * Distributed by Healthways Food Center * * * Portland 4, Oregon"; (drum) "Safflower Oil Edible CP"; (pkg.) "Hain Safflower All Vegetable Spread The Liquid Safflower Oil Used Is Unsaturated * * * Distributed by Hain Pure Food Company, Inc., Los Angeles, Calif."; (ctn.) "Sona Vegetable Margarine * * * Whipped Made from 100% Safflower Oil * * * Distributed by Sona Food Prod. Co., Los Alamitos, Calif. * * * Four Cubes."

ACCOMPANYING LABELING: Books entitled "Calories Don't Count" by Herman Taller, M.D.; display sheets entitled "Calories Don't Count News About A Revolutionary Reducing Plan"; placards entitled "You've Read About Them For Reducing," "Yes! We Have Safflower Capsules," "Shop Healthway Downtown & Lloyd Center For Highest Potency Safflower Oil Caps," "Our Safflower Oil Guaranteed," "Compare Potency & Prices! Our Safflower Capsules," "Our Safflower Margarine is made with 100% Pure Saff Oil," and "Safflower Oil No Preservatives"; and newspaper clippings reading in part "Safflower Oil Comes Into Its Own."

RESULTS OF INVESTIGATION: The capsules and the oil were shipped in bulk to the dealer, who redelivered the drums to local jobbers for repacking into retail bottles. The articles were returned to the dealer in the retail bottles and the bulk drums remained in the possession of the jobbers.

The placards were prepared by, and printed locally for, the dealer, and all of the accompanying labeling was used by the dealer in promoting sales of the articles, either as part of window displays of the articles or by displaying in the dealer's retail stores.

LIBELED: 6-12-62, Dist. Oreg.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the articles (bulk and repack) contained false and misleading representations that the capsules were of significant value for special dietary supplementation by reason of the presence therein of safflower oil; and that all the articles were adequate and effective for the control of body weight and to reduce and to maintain slimness, even though consuming many thousands of calories daily without regard to the total caloric intake; to lower and to control the cholesterol level of the blood; for the treatment and prevention of arteriosclerosis, heart disease, diabetes, and heartburn; to improve the complexion; increase resistance to colds and sinus trouble; promote health; and increase sexual drive.

DISPOSITION: On 9-5-62, a stipulation was entered and allowed by the court whereby the drums of oil under seizure were released without adjudication to the claimant, Healthfoods, Inc., on a showing that the article was perishable and under the conditions that the article was released for food use only; that no therapeutic claims of any kind would be made for the food products; that the food products would not be associated with any promotional material representing and suggesting that the article was adequate and effective for the purposes charged in the libel; that the products would not be associated with the book "Calories Don't Count" or with any of the display sheets, placards, or newspaper clippings referred to in the libel; and that the contents of the drums would not be used to manufacture capsules.

On 10-15-62, Healthfoods, Inc., was permitted to withdraw its claim. A default decree was entered, on 11-2-62. The bottles of oil, and the margarine and spread were delivered to a charitable institution for its use; the books

"Calories Don't Count" were delivered to the Food and Drug Administration for official purposes; and the capsules and the remaining literature were destroyed.

7401. Various safflower oil and gluten products. (F.D.C. No. 47440. S. Nos. 5-522/3 T, 5-525 T, 5-527/30 T.)

QUANTITY: 33 1-pt. btls. of *safflower oil*, 22 1-pt. btls. of *safflower mayonnaise*, 18 100-capsule btls. of *safflower oil capsules*, 46 12-oz. pkgs. of *gluten self-rising flour*, 12 3-oz. pkgs. of *gluten noodles*, 10 3-oz. pkgs. of *gluten spaghetti*, and 10 3-oz. pkgs. of *gluten macaroni*, at Richmond, Va., in possession of Thalhimers Department Store.

SHIPPED: Between 2-7-62 and 3-30-62, from New York, N.Y., by Balanced Foods, Inc., and (*safflower mayonnaise* only) from North Hollywood, Calif., by Dynamic Nutritional Products.

LABEL IN PART: (Btl.) "Hain Saf-Flower Seed Oil * * * Contains 74% to 79% Poly-Unsaturates * * * Distributed by Hain Pure Food Company, Inc. Los Angeles, Calif."; (btl.) "Balanaise 100% Saf-flower Mayonnaise * * * Polyunsaturated Low Cholesterol Prepared without salt * * * Formulated by Balanced Food Inc. Dist. New York 3 N.Y."; (btl.) "100 Noble 1150 Mgs. Safflower Oil Capsules with 10 Mgs. B-6 Noble Nutritional Foods, Inc. Dist. New York, N.Y. Each Capsule Contains"; (pkg.) "Be Diet-Wise with Dia-Mel No Salt Added dietetic self-rising (gluten) flour specially prepared for low sodium and starch restricted diets 3 Sealed Packets * * * Ingredients * * * Packed by Dietetic Food Co., Inc., Brooklyn, N.Y."; (pkg.) "Dia-Mel dietetic Gluten Noodles * * * Specially prepared for starch restricted diets Packed by Dietetic Food Co., Inc., Brooklyn 19, N.Y."; (pkg.) "Dia-Mel dietetic Gluten Spaghetti Specially prepared for starch restricted diets No Salt Added * * * Packed by Dietetic Food Co., Inc., Brooklyn, N.Y."; and (pkg.) "Dia-Mel dietetic Macaroni elbow style made from Gluten Flour Specially prepared for starch restricted diets * * * Packed by Dietetic Food Co., Inc., Brooklyn, N.Y."

ACCOMPANYING LABELING: Book entitled "Calories Don't Count" by Herman Taller, M.D.; placards reading in part "For the newest fashion in dieting . . . Safflower Oils and Gluten Breads" and "Recommended For Slimming Diets Safflower Oil, Safflower Capsules, Gluten Flour, Gluten Toast."

RESULTS OF INVESTIGATION: The book named above was used in promoting sales of the articles containing safflower oil; the above placards were prepared on order of the dealer, and were used in promoting sales of all of the articles.

LIBELED: 4-9-62, E. Dist. Va.; libel amended 4-12-62.

CHARGE: 502(a)—when shipped and while held for sale, the bottle and package labels, and the accompanying labeling, contained false and misleading representations that the articles were adequate and effective to reduce body weight; and that the *safflower oil*, *safflower mayonnaise*, and *safflower oil capsules* were adequate and effective to reduce body weight even though consuming thousands of calories daily without regard to the total caloric intake; to lower and control the cholesterol level of the blood; for the treatment and prevention of arteriosclerosis, heartburn, heart disease, high blood pressure, and diabetes; to improve the complexion; to increase resistance to colds and sinus trouble; promote health; and increase sexual drive.

The libel alleged also that the *safflower oil capsules* and the various gluten products were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: On 5-9-62, the articles were claimed by Balanced Foods, Inc., New York, N.Y., and an answer was filed by Balanced Foods, Inc., denying that the articles were misbranded. Thereafter, the case was removed to the Eastern District of New York. On 5-25-62, Dietetic Food Co., Inc., answered the libel and denied that the products packed by them, namely, the *gluten self-rising flour*, *noodles*, *spaghetti*, and *macaroni*, were misbranded. On 6-25-62, Balanced Foods, Inc., withdrew its claim to the goods. On or about 6-28-62, Dietetic Food Co., Inc., filed a claim to the *gluten self-rising flour*, *noodles*, *spaghetti*, and *macaroni*. On 8-3-62, a default decree of condemnation and destruction was filed with respect to the *safflower oil*, *mayonnaise*, and *capsules*. On 8-14-62, such articles were destroyed. On 1-3-63, the action with respect to the *gluten self-rising flour*, *noodles*, *spaghetti*, and *macaroni* was dismissed, without prejudice, upon the motion of the United States attorney on the grounds that these articles constituting the res of the action were no longer in existence, since they had been inadvertently destroyed, thereby rendering the action moot.

7402. Lecitabs (lecithin tablets). (F.D.C. No. 48127, S. No. 65-297 T.)

QUANTITY: 120 90-tablet btl., 144 180-tablet btl., and 118 540-tablet btl., at Glendale, Calif.

SHIPPED: 7-25-61 and 8-1-62, from Chicago, Ill., by National Lecithin, Inc.

LABEL IN PART: "National Lecitabs Lecithin Tablets * * * Ingredients: Soya Lecithin, in a base of non-fat, dry milk solids and soy protein. Natural flavoring added. Sole Distributors: National Lecithin, Inc. Chicago 26, Ill. * * * a dietary supplement of natural lipotropic factors. * * * as an aid in lowering blood cholesterol."

LIBELED: 10-9-62, S. Dist. Calif.

CHARGE: 502(a)—when shipped, the label of the article contained false and misleading representations that the article was adequate and effective to promote the utilization of fat and to lower blood cholesterol.

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 1-29-63. Default—destruction.

7403. Sea salt. (F.D.C. No. 46702, S. No. 14-315 R.)

INDICTMENT RETURNED: 5-16-62, S. Dist. Tex., against United Salt Corp., Houston, Tex., and Lorne F. Van Stone.

SHIPPED: 1-28-61, from Texas to Ohio.

LABEL IN PART: (Ctn.) "Admiral Natural Mineral Sea Salt * * * Mfgd. by United Salt Corporation Houston, Texas."

ACCOMPANYING LABELING: Leaflets entitled "100% Sea Salt With All The Natural Minerals"; booklets entitled "Cal October 1960" and "The Ocean's 44 Trace Chemicals."

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article would be adequate and effective in the treatment and prevention of cancer, diabetes, multiple sclerosis, myasthenia gravis, muscular dystrophy, epilepsy, asthma, arthritis, insanity, deficiency ailments, allergies, Parkinson's disease, arteriosclerosis, schizophrenia, cataracts, cirrhosis, leukemia, pernicious anemia, psoriasis, dental caries, baldness, sterility, goiter, acne, and grey hair; that the article was a "chemical smorgasbord" supplying significant amounts of

minerals necessary for body glands and organs to provide good health; that the article would be beneficial for growth, lactation, and reproduction; that the article was a complete and balanced salt, supplying significant amounts of all the trace minerals and essential minerals for special dietary and therapeutic purposes; that all the trace minerals in the article had been established as essential and important to good health; and that foods, as consumed, are lacking in all the trace minerals contained in the article.

PLEA: Guilty.

DISPOSITION: 7-13-62. Corporation—\$1,000 fine; individual—\$1,000 fine.

7404. Sea kelp powder and Kelp-Ettes. (F.D.C. No. 46561. S. No. 21-857 R.)

QUANTITY: 70 100-lb. drums of *sea kelp powder* and 397 100-tablet btl. of *Kelp-Ettes*, at Hobart, Ind., in possession of Nelson's Natural Foods.

SHIPPED: The bulk sea kelp was shipped on 3-8-61, from San Pedro, Calif.

LABEL IN PART: (Btl.) "500 5 Grain Tablets * * * Nelson's Kelp-Ettes A Pure Sea Food Containing Safe Natural Iodine. Made from Pacific Coast Giant Brown Sea-Kelp (*Macrocystis Pyrifera*) * * * Packed and Distributed by: Nelson's Natural Foods."

ACCOMPANYING LABELING: Leaflets entitled "Have You Checked Your Eating Habits Lately?"; mimeographed sheets entitled "Alcohol or Poor Diet," "Who is More Important? A New Born Baby or You? Think It Over!" and "Do You Play the Game of Life to Win?"

RESULTS OF INVESTIGATION: The accompanying leaflets and mimeographed sheets were used by the dealer in promoting the sales of the article. The *Kelp-Ettes* had been prepared and entabled by the dealer using a portion of the bulk powder.

LIBELED: 10-10-61, N. Dist. Ind.

CHARGE: 502(a),—while held for sale, the accompanying labeling of the article contained false and misleading representations that the article was adequate and effective for the treatment and prevention of cirrhosis of the liver, dizziness, lack of coordination, thyroid conditions, overweight and underweight conditions, tiredness, rundown feeling, and to promote health, vigor, and long life.

The libel alleged also that the article was misbranded under provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: On 12-21-61, Carl A. Nelson, owner and operator of Nelson's Natural Foods, filed an answer consenting to a decree. On 1-24-62, a consent decree of condemnation was entered. On 2-7-62, the articles were released under a \$500 bond to the claimant for the purpose of bringing the article into compliance with the law. On 9-20-62, a motion was filed to declare forfeiture of bond, which motion was based upon claimant's failure to keep the seized lot intact for examination and inspection, in that claimant made 3 shipments of sea kelp without notification to, or authorization from, a representative of the Department of Health, Education, and Welfare. On 10-25-62, the Government's motion was argued before the court and the court declared the bond forfeit. On 10-31-62, a decree of forfeiture was filed.

7405. BPI tablets. (F.D.C. No. 48366, S. Nos. 92-183 T, 92-193 T.)

QUANTITY: 1 btl. containing 150 tablets at Tarentum, Pa., in possession of a pharmacy, and 10 1,000-tablet btl., and 1 btl. containing 876 tablets, in possession of Howard B. Emerson, M.D., Tarentum, Pa.

SHIPPED: Prior to 7-15-61 and on 3-26-62, from Kalamazoo, Mich.

LABEL IN PART: (Btl.) "Special Formula 1000-Tablets C.T. Indigo Each Tablet Contains: Biotin 0.1 Mg. PABA (Para-aminobenzoic acid) 50.0 mg. Inositol 250.0 mg. Usual dose. 1 tablet."

ACCOMPANYING LABELING: Leaflets entitled "BPI Pills."

RESULTS OF INVESTIGATION: The tablets were manufactured for Howard B. Emerson, M.D., who also ordered the leaflets printed.

LIBELED: 11-15-62, W. Dist. Pa.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for any chronic bacterial infections due to common pathogens, such as streptococcus, pneumococcus, and bacillus coli.

DISPOSITION: 1-4-63. Default—destruction.

7406. Kel-Zyme capsules. (F.D.C. No. 47734. S. No. 184 T.)

QUANTITY: 20 100-capsule btls. and 8,474 capsules in bulk container, at Sarasota, Fla., in possession of Kahlenberg Laboratories.

SHIPPED: 10-25-61, from Long Island City, N.Y.

LABEL IN PART: (Btl.) "Kel-Zyme Each capsule contains 0.22 gm. Trypsin 1/125. Dose: 2 capsules after each meal * * * Kahlenberg Labs. Sarasota Fla."

RESULTS OF INVESTIGATION: The article was shipped in bulk and repacked into bottles, as described above, by Kahlenberg Laboratories.

LIBELED: 7-18-62, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the bottle label contained false and misleading representations that the article was adequate and effective as a treatment for relieving or overcoming noninfectious skin disorders, generalized psoriasis, atopic eczema, neurodermatitis, cancerous cachexia, and infantile eczema.

DISPOSITION: 1-3-63. Default—destruction.

7407. Imitation Serpasil tablets. (F.D.C. No. 47085. S. Nos. 67-602 R, 67-694 R.)

INFORMATION FILED: 9-6-62, E Dist. Tex., against Norman Ray, t/a Ray Pharmacy, Henderson, Tex.

ALLEGED VIOLATIONS: Between 1-1-60 and 4-3-61, while a number of *imitation Serpasil tablets* were being held for sale after shipment in interstate commerce, the defendant caused a number of tablets to be offered for sale and sold as Serpasil, and also caused a number of tablets to be repacked into a bottle labeled Serpasil, which acts resulted in the drug being misbranded.

CHARGE: 502(a)—the statement "Tablets 0.25 mg. each SERPASIL * * * CIBA" appearing on the bottle was false and misleading in that it represented that the drug consisted of Serpasil tablets, whereas it consisted of *imitation Serpasil tablets*; 502(i) (2)—the article was an imitation of another drug, Serpasil; and 502(i) (3)—the article was offered for sale under the name of another drug, namely, Serpasil.

PLEA: Guilty.

DISPOSITION: 12-19-62. \$400 fine.

7408. Specifex Adrenal Hormone Cream. (Inj. No. 408.)

COMPLAINT FOR INJUNCTION FILED: 2-12-62, E. Dist. Mo., against Specifics Drug Co., a partnership, Affton, Mo.; Monte C. Etherton and Frank L. Etherton, partners in the partnership; Kantol Packaging Co., a corporation, St. Louis, Mo.; and Gustav C. Schuricht, t/a Schuricht's, Affton, Mo.

LABEL IN PART: "Specifex Adrenal Hormone Cream * * * Epinephrine Hydrochloride U.S.P. * * * For External Use * * * Specifics Drug Co. No. 44 Montague, St. Louis 23, Mo."

ACCOMPANYING LABELING: Leaflets entitled "Read First! How Enclosed Sample May Help Relieve Pain in Stiff, Sore Muscles and Joints," "For Stiff, Sore Muscles or Joints * * * The Treatment of Chronic Rheumatism," and "A Clinical Study Regarding The Use of Epinephrine Cream (1:5000) In Human Subjects"; and an order blank reading in part "Specifics Drug Co. * * * Rush By Return Mail * * * Works Like a Shot!"

NATURE OF BUSINESS: In the conduct of business concerning the above-named drug, the defendants performed the following operations:

(a) Specifics Drug Co., under the direction of Monte and Frank Etherton, arranged for and directed the manufacture, labeling, and distribution of the drug;

(b) Gustav C. Schuricht assembled and mailed the labeling, together with quantities of the drug in jars and plastic containers, to persons whose names and addresses appeared on mailing lists supplied by Specifics Drug Co.;

(c) Kantol Packaging Co. manufactured the drug and packed it into jars and plastic containers. Kantol Packaging Co. placed the jars in shipping containers together with copies of an order blank reading in part "Specifics Drug Co. * * * Rush by Return Mail * * * Works Like a Shot!" and delivered the drug, so packaged, to Gustav C. Schuricht. The plastic containers were delivered by Kantol Packaging Co. to Gustav C. Schuricht.

CHARGE: The complaint alleged that the defendants were causing to be introduced into interstate commerce, the above-named article which was misbranded under 502(a) in that its labeling contained false and misleading representations that the article was an adequate and effective treatment for relieving or overcoming rheumatic and other arthritic pains; pains of fibrositis due to sprains, strains, fractures, and postoperative adhesions; knots and swellings, arthritis, chronic fibrositis, rheumatism and arthritic afflictions, lumbago, relief of the pain of shingles, skin blemishes—keratoses of the aged, gout, painful skin and nerve conditions, obstinate and painful conditions, lameness, migraine headaches, trifacial neuralgia, rheumatoid arthritis or serositis, frozen nerves, neuritis, sciatica, charleyhorse, gouty neuritis, chronic rheumatism, neuralgia, relief from pain and stiffness, osteoarthritis, stiff and painful fingers, and capsulitis.

The complaint alleged further that if the defendant was merely restrained from introducing into interstate commerce, any of the drug with false and misleading labeling the defendant would not discontinue interstate distribution of the drug but would continue to ship the drug in interstate commerce, without specifying in its labeling the purposes and conditions for which the drug was intended. In such case, the drug would be misbranded under 502(f) (1) in that its labeling would not bear adequate directions for use because of the omission from its labeling of the purposes and conditions for which the drug was to be used.

DISPOSITION: 6-1-62. The defendants having consented, the court entered a decree of permanent injunction enjoining the defendants from directly or indirectly doing the following acts:

(a) Introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, the drug designated as *Specifex Adrenal Hormone Cream*," or any similar drug, when accompanied by the following written, printed, or graphic matter, or by any written, printed, or graphic matter substantially to the same effect: (1) a leaflet entitled "Read First! How Enclosed Sample May Help Relieve Pain in Stiff, Sore Muscles and Joints."; (2) a leaflet entitled "For Stiff, Sore Muscles or Joints * * * The Treatment of Chronic Rheumatism."; (3) a leaflet entitled "A Clinical Study Regarding The Use of Epinephrine Cream (1:5000) in Human Subjects."; and (4) an order blank reading in part "Specifics Drug Co. * * * Rush by Return Mail * * * Works Like A Shot!"

(b) Introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, a drug designated as "*Specifex Adrenal Hormone Cream*," or the same drug by any other designation, or any drug containing epinephrine (adrenalin), or any similar component, bearing or accompanied by any written, printed, or graphic matter which states, represents, suggests or implies that such drug is adequate and effective by reason of the presence of the epinephrine (adrenalin), or any similar component, on the basis of any claims, direct or indirect, made on behalf of the epinephrine (adrenalin), or similar component contained in the product, for relieving or overcoming rheumatic and other arthritic pains; pains of fibrositis due to sprains, strains, fractures, and postoperative adhesions; knots and swelling, arthritis, chronic fibrositis, rheumatism and arthritic afflictions, lumbago, relief of the pain of shingles, skin blemishes—keratoses of the aged, gout, painful skin and nerve conditions, obstinate and painful conditions, lameness, migraine headaches, trifacial neuralgia, rheumatoid arthritis or serositis, frozen nerves, neuritis, sciatica, charleyhorse, gouty neuritis, chronic rheumatism, neuralgia, relief from pain and stiffness, osteoarthritis, stiff and painful fingers, and capsulitis; or which is otherwise false and misleading;

(c) Introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, the drug designated as "*Specifex Adrenal Hormone Cream*," or any similar drug, which fails to bear labeling stating every disease, condition, and purpose for which such drug is represented and for which it is intended to be used; and

(d) Delivering or causing to be delivered for use as labeling for the article of drug designated as "*Specifex Adrenal Hormone Cream*," or any similar drug, any of the aforesaid written, printed, or graphic matter described in subparagraphs (a) and (b) above.

7409. Lix-Pain cream liniment. (F.D.C. No. 48084. S. No. 84-806 T.)

QUANTITY: 156 4-oz. btls. at Sonoma, Calif., in possession of Martin's Service.

SHIPPED: 6-29-62, from Kinston, N.C., by Oglesby Chemical Co.

LABEL IN PART: "Lix-Pain Cream Liniment * * * Active Ingredients: Ammonium carbonate, Camphor, Turpentine, Thyme, Lanolin. Caution: * * * Manufactured by Oglesby Chemical Company, Kinston, North Carolina."

ACCOMPANYING LABELING: Leaflets entitled "Welcome! To the Prospective Users of Lix-Pain," "Sample Orders," and "Agents Wanted 100% Profit"; and postcard entitled "100% Profit—Plus Tremendous Repeat Business."

RESULTS OF INVESTIGATION: The leaflets entitled in part "Welcome" were supplied by the manufacturer. The other literature was prepared by the dealer for the purpose of promoting sales of the article.

LIBELED: 9-7-62, N. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the label and the accompanying labeling contained false and misleading representations that the article was adequate and effective to relieve muscular soreness, rheumatic pains, swollen glands, arthritis, sinus, neuralgia, backache, headache, and bruises and sprains; would in many cases give complete absence of pain; quickly relieve miseries and pains of neuritis, burns, swollen joints, and many other ills; would soothe pains and irritated areas; quiet nerves; and promote sleep, rest, and enjoyment of life.

DISPOSITION: 12-21-62. Default—destruction.

7410. Dr. Reeves' Special Foot Cream. (F.D.C. No. 47196. S. No. 28-056 T.)

QUANTITY: 587 jars at Kansas City, Mo.

SHIPPED: 1-31-62, from Olathe, Kans., by Chemical Commodities, Inc.

LABEL IN PART: "Dr. Reeves' Special Foot Cream for Diabetics * * * Contains Lanolin, Menthol and Methyl Salicylate * * * 2 Oz. Dr. Reeves' Products, Inc., 809 Wyandotte Kansas City 6, Mo."

RESULTS OF INVESTIGATION: Examination showed that the article was short weight.

LIBELED: On or about 3-7-62, W. Dist. Mo.

CHARGE: 502(a)—when shipped, the label of the article bore false and misleading representations that the article was adequate and effective for the treatment of impaired foot circulation and prevention of corns and calluses; and 502(b) (2)—the article failed to bear a label containing an accurate statement of the quantity of contents.

DISPOSITION: 12-21-62. Default—destruction.

7411. A-Gic Jel. (F.D.C. No. 44592. S. No. 6-511 R.)

QUANTITY: 240 cases, each containing 24 individually ctn'd. 2-oz. jars, and 12 2-oz. jars without ctns., at Hamden, Conn., in possession of A-Gic Laboratories, Inc.

SHIPPED: 9-21-59 and 1-29-60, from New York, N.Y.

LABEL IN PART: (Jar) "A-Gic A permanent jel of Aloe leaf * * * Distributed by A-Gic Laboratories, Inc., * * * Mt. Carmel, Conn. Active Ingredient is pulp of freshly plucked Aloe Vera Leaf (78%). Compounded with Glycerin, Gum Tragacanth, Sodium Benzoate and Sodium Bi-sulphite."

ACCOMPANYING LABELING: Leaflets entitled "A-Gic Leaflet A-1" and "Professional Bulletin A-Gic"; streamers reading in part "A-Gic * * * For Sunburn for Poison Ivy" and "A-Gic * * * For Skin Irritation For Detergent Hands"; and counter display cartons reading in part "A-Gic Stops Skin Itch Instantly."

RESULTS OF INVESTIGATION: The jars of the article were placed in cartons with the leaflet "A-Gic Leaflet A-1," by the dealer. The accompanying labeling was used by the dealer in the sale and distribution of the article.

LIBELED: 6-4-60, Dist. Conn.

CHARGE: 502(a)—while held for sale, the carton label and the accompanying labeling contained false and misleading representations that the article was

an adequate and effective treatment for all types of burns, cuts, abrasions, skin irritations, poison ivy, superficial ulcers, athlete's foot, and skin itch; would induce rapid healing; prevent formation of scar tissue; and was anti-septic.

DISPOSITION: 8-22-62. Consent—claimed by A-Gic Laboratories, Inc., for relabeling.

7412. 'BST'-SOL injections. (F.D.C. No. 46485. S. Nos. 53-802/3 R.)

QUANTITY: 472 30-cc. vials and 350 10-cc. vials at Minneapolis, Minn.

SHIPPED: Between 6-30-59 and 3-9-61, from Dayton, Ohio, by Durr Products, Inc.

LABEL IN PART: (Ctn. and vial) "30 cc Sterile Solution * * * Multiple Dose Vial 'BST'-SOL (Canfield) 3% * * * Each cc. represents an Aqueous Solution of Bismuth Sodium Tartrate (B.P.) 3% Sucrose 0.250 Gm Benzyl Alcohol 2% FOR INTRAMUSCULAR USE ONLY (PVDC) For Veterinary Use Only. See insert for indications and dosage. Caution: * * * PROFESSIONAL VETERINARY Drug Co. Minneapolis, Minnesota" and "10 cc Sterile Solution * * * Multiple Dose Vial Trade-mark 'BST'-SOL (canfield) 3% Each cc. represents An Aqueous solution of: Bismuth Sodium Tartrate (B.P.) 3% Sucrose 0.250 Gm Benzyl Alcohol 2% For Intramuscular Use Only. Caution: * * * C. R. Canfield & Co. Minneapolis, Minn."

ACCOMPANYING LABELING: Leaflets entitled "In The Clinical Veterinary Field Use in Specific Pathosis 'BST'-SOL (Canfield)" and "Canfield 'BST'-SOL."

RESULTS OF INVESTIGATION: The 30-cc. vials were intended for veterinary use and the 10-cc. vials for human use.

LIBELED: 10-20-61, Dist. Minn.

CHARGE: 30-cc. 'BST'-SOL, 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective as a treatment for all virus infections of animals and prevented complications of the central nervous system in distemper; and the accompanying labeling also contained representations that the article was an adequate and effective treatment for lichen planus, scleroderma, lupus erythematosus, condylomata, acuminata, and acne in animals which representations were false and misleading since the conditions named are not found in domestic animals.

10-cc. 'BST'-SOL, 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective as a treatment for virus pneumonia, acute infectious hepatitis, acute infectious mononucleosis, chicken pox (severe form), measles (severe form), mumps, herpes zoster, herpes simplex, and verrucae.

DISPOSITION: On 11-29-61, C. R. Canfield & Co., Inc., claimed the articles and denied that they were misbranded. On 2-28-62, the Government served interrogatories on the claimant. On 1-24-63, a consent decree of condemnation, in which the claimant neither admitted nor denied the allegation of the libel, was filed; and, thereafter, the articles were relabeled.

7413. Visible Spectrum Color Projector. (Inj. No. 325.)

COMPLAINT FOR INJUNCTION FILED: 11-27-57, Dist. N.J., against Visible Spectrum Research Institute, a corporation, Malaga, N.J., and Dinshah P. Ghadiali, president, treasurer, and trustee of the corporation.

NATURE OF DEVICE: The device designated as *Visible Spectrum Color Projector* was made in two models, one of which was portable. The larger device, which sold for \$125, consisted essentially of a cabinet on a stand. Inside the cabinet was a 1,000-watt electric light bulb, a small electric fan (for cooling), a glass bottle for holding water, and two condensing lenses. Attached to the front of the cabinet was a carrier containing colored slides of glass. These slides could be moved back and forth so that a single color slide or a combination of two color slides could be used, through which the light rays from the bulb inside the cabinet would shine on the part of the body to be treated. The portable device had a 500-watt electric bulb and sold for \$60.

The above-mentioned device was similar to the device designated as "Spectro-Chrome" which had twice been adjudged worthless for use in the cure, mitigation, treatment, and prevention of the ills of mankind, namely, in seizure proceedings instituted on 8-11-44, and in criminal proceedings instituted on 8-7-45, and reported in notices of judgment on drugs and devices, Nos. 2098 and 2389, respectively.

NATURE OF DEFENDANTS' BUSINESS: The complaint alleged that the defendants were the interstate promoters and distributors of the device, and in connection with such business they employed various pieces of accompanying labeling consisting of: "Visible Spectrum Instructor," "Respiratory Rhythm Guide," "Family Health Protector," "Visible Spectrum Researcher"—various monthly issues, "Spectro-Chrome Metry Encyclopedia"—3 volumes, "Personal Research Information" (white and pink sheets), "Constitution and By-Laws," "Cook Book," and "Capsule News"; that the promotion and distribution of the device was carried on through the medium of Visible Spectrum Research Institute; that groups which included only members of the Institute would meet monthly in several cities of the United States; that these groups were called "studios," formerly "planets"; that a "student" must read the "Family Health Protector" and pay \$3 annual dues; that thereafter a "student" may become a "researcher" and must read volume 1 of the "Spectro-Chrome Metry Encyclopedia," buy a *Visible Spectrum Color Projector*, and pay \$6 annual dues; that thereafter a researcher may become a "graduate researcher" and in addition to the above requirements must take a course in "Visible Spectrum Research" under the guidance and direction of Dinshah Ghadiali, for which \$150 was charged; that component parts for the device were shipped to Malaga, N.J., from points outside the state and were assembled in Malaga at the Institute where the various items of accompanying labeling referred to above came into association with the device; that the assembled devices, parts therefor, and labeling were shipped by the Institute from Malaga, N.J., to various places outside of New Jersey; that the accompanying labeling was sent to owners and prospective owners of the device; that substantially all of the business functions connected with the promotion and sale of the device were carried on and performed by Dinshah Ghadiali who was the inventor and originator of the color projector, the editor of "Visible Spectrum Researcher," a monthly magazine, and the author of all editorial remarks therein, and the author of the "Spectro-Chrome Metry Encyclopedia," in 3 volumes; and that Dinshah Ghadiali would personally answer requests for advice from members of the Institute directing what color or colors to use and making additional suggestions which he determined best suitable for the treatment of the affliction indicated in the requests.

CHARGE: The complaint alleged further that the device, when caused to be introduced and delivered for introduction into interstate commerce by the defendants, was misbranded under 502(a) in that the device was accompanied by labeling which falsely represented and suggested that the device was capable of preventing, mitigating, treating, and curing the ills of mankind.

DISPOSITION: On 11-27-57, the court entered a temporary restraining order against the defendants enjoining them from introducing into interstate commerce, and particularly from delivering to any "student," "researcher," "graduate researcher," and other member or associate of Visible Spectrum Research Institute living outside the State of New Jersey, for transportation in interstate commerce, the device known as "*Visible Spectrum Color Projector*," the components, parts and accessories therefor, and any other device of similar construction and use which (a) have as items of accompanying labeling, the following, but not limited thereto, namely: the "Visible Spectrum Instructor," "Respiratory Rhythm Guide," "Family Health Protector," "Visible Spectrum Researcher," "Spectro-Chrome Metry Encyclopedia" or any of its volumes, "Personal Research Information" (white and pink sheets), "Constitution and By-Laws," "Cook Book," labels for the devices, and "Capsule News"; (b) are represented or suggested in their labeling, or otherwise, to be capable of curing, mitigating, treating, or preventing any of the ills of mankind; or (c) are misbranded within the meaning of 502(a) by reason of any false or misleading representation or suggestion in the labeling of the devices.

The temporary restraining order further enjoined the defendants from promoting the sale, distribution, or use of any such device in interstate commerce by means of written, printed or graphic matter.

The restraints contained in the temporary restraining order were continued in effect by the court from time to time by agreement of the parties.

A motion for summary judgment was subsequently filed by the Government. On 9-17-58, it appearing to the court from the pleadings, the affidavits attached thereto, the exhibits, and the requests for admissions and the answers thereto, that there was no genuine issue as to any material fact and that the Government was entitled to judgment as a matter of law, the court ordered that summary judgment be entered in favor of the Government and that the temporary restraining order, of 11-27-57, be made permanent.

7414. Selectronair air purifier device. (F.D.C. No. 45948. S. Nos. 38-709 R, 38-711 R.)

QUANTITY: 8 devices at Philadelphia, Pa.

SHIPPED: 2-27-61 and 4-14-61, from Shelton, Conn., by Selectronair, Inc.

LABEL IN PART: (Ctn.) "Selectronair Air Purifier * * * Distributed by Selectronair, Incorporated, Shelton 8, Conn."

ACCOMPANYING LABELING: Booklet entitled "Breathe and Sleep, by Edward S. Cornell, Jr.": leaflet entitled "Only Selectronair Purifies"; booklet entitled "Only Selectronair Sanitizes."; and placard entitled "Selectronair Selects and Sanitizes the Air You Breathe."

RESULTS OF INVESTIGATION: Examination indicated that the article was an air circulator made of a motor and two centrifugal blowers. Associated with each blower was a filter and three ultraviolet lamps. Air was pulled through the filter, irradiated with ultraviolet and blown out through a directionally controlled exhaust portal.

LIBELED: 6-13-61, E. Dist. Pa.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective as a treatment for relieving hay fever, pollen asthma, sinus conditions, allergies, and respiratory ailments; providing completely germ-free air in every corner of every room; reducing colds, sore throats, and respiratory ailments; preventing cross-contamination of respiratory ailments; and destroying airborne bacteria and germs associated with the common cold and preventing sore throats.

DISPOSITION: On 7-11-61, Selectronair, Inc., filed a claim to the article, and answered denying that the article was misbranded. The claimant also served a set of interrogatories and a motion to produce a copy of the analysis on which the proceedings by the Government had been based. Subsequently, the Government answered the claimant's interrogatories and voluntarily furnished the claimant with the analysis requested. On 7-26-61, the claimant's motion to produce a copy of the analysis was dismissed. The Government thereafter served interrogatories upon the claimant. On 7-5-62, the claimant having consented to the entry of a decree without admitting any of the ultimate facts in controversy and for the purpose of avoiding the trouble and expense of further litigation, judgment was entered providing for condemnation of the article and its release under bond for the purpose of bringing the article into compliance with the law and destroying the accompanying labeling.

7415. Emerson Ionator device. (F.D.C. No. 48403. S. No. 12-569 V.)

QUANTITY: 91 devices at Chicago, Ill.

SHIPPED: 9-14-62, from Jersey City, N.J., by Emerson Radio & Phonograph Corp.

LABEL IN PART: "Emerson Ionator Air Purifier Negative Ionizer * * * Model EP 40 * * * A Product of Emerson Radio and Phonograph Corp."

ACCOMPANYING LABELING: Leaflets entitled "The Emerson Ionator World's First Air Health Conditioner" and "The Emerson Electronic Ionator."

RESULTS OF INVESTIGATION: Investigation indicated the article to be a metal cabinet 12" by 19" by 10" with a metal mesh panel in the front. The cabinet contained two fiber glass filters, an electrostatic filter, a negative ion generator, high voltage power supplies, circulating fan, and control knobs on the front panel.

LIBELED: 12-11-62, N. Dist. Ill.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective to control and relieve respiratory ailments, asthma, hay fever, and colds; that negative ions had been recently established as a key factor in the control and relief of respiratory ailments such as asthma, hay fever, colds and similar allergies; that the article health-conditioned the air by putting negative ions in; that it would control and relieve asthma, hay fever, dust, and pollen allergies; that correct negative ionization of the air was of great importance to personal health; that an abundance of negative air ions (air molecules that have extra electrons) in the air we breathe had a stimulating effect on the respiratory system that added to general well-being and comfort and brought relief to allergy sufferers; that negative ions sped the cleaning action of the

cilia in the bronchial tubes, trachea, windpipe and nasal passages, thus tending to loosen mucous, increasing its beneficial flow, and causing the relaxation of the underlying muscles of the air ducts; that negative ions helped counteract the effects of positive ions which were the cause of "washed-out" feelings; that positive ions brought on irritability, tiredness, even headaches, and that the article, by filtering the air and simultaneously generating negative ions to offset the positive ions, produced a cleaner, healthier, more comfortable atmosphere.

DISPOSITION: 2-4-63. Consent—claimed by Emerson Midwest Corp., and relabeled.

7416. **Pentronaire devices and Humi-Zon devices.** (F.D.C. No. 45525. S. Nos. 99-584/5 R.)

QUANTITY: 80 *Pentronaire devices* and 70 *Humi-Zon devices* at Boston, Mass.

SHIPPED: Between 10-1-60 and 10-31-60, from Chicago, Ill., by Pentron Sales Co., Inc.

LABEL IN PART: "Pentronaire Model * * * Pentron Sales Co., Inc. Subsidiary of Pentron Electronics Corporation Chicago, Illinois" and "Humi-Zon Pentron."

ACCOMPANYING LABELING: Leaflets entitled "Makes Indoor Air outdoor fresh—the new Pentronaire Purifier," "New Pentronaire Purifier," "The Pentronaire Product Story," "Product Information Program—The Humi-Zon Humidifier Model HZ-500," "Humidify without steam with a Humi-Zon," and "now protect health and comfort with Humi-Zon"; and placards entitled "Humi-Zon by Pentron" and "New Pentronaire Purifier."

RESULTS OF INVESTIGATION: Examination indicated that the *Pentronaire device* consisted of a metal box-like cabinet containing an electric fan, an ultraviolet lamp, an aluminum mesh filter, and a baffle plate. In operation, room air was drawn into the unit by the fan, blown past the ultraviolet lamp through the filter, striking the baffle plate, and ejected into the room. The *Humi-Zon device* consisted of a metal box-like cabinet containing a fiber glass filter pad, an electric fan, a series of eleven plastic impregnated baffles or wicks, and a water reservoir accessible through the top of the cabinet. In operation, the fan drew room air into the cabinet, through the fiber glass filter, and over the wicks which were moist with water from the reservoir. The moist air was then blown from the cabinet into the room.

LIBELED: 3-23-61, Dist. Mass.

CHARGE: *Pentronaire device*, 502(a)—when shipped, the accompanying labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for relieving respiratory ailments and allergies; that it enabled one to sleep more soundly and work more efficiently; that it would purify the air with a degree of efficiency comparable to that of sunlight; and that it would destroy most airborne bacteria.

Humi-Zon device, 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective in preventing colds, coughs, sore throat, postnasal drip, muscle spasm, irritation of nasal passages, respiratory diseases, and the presence of disease-causing bacteria in the nasal passages; and that the article would aid the body's natural resistance to disease, prevent dangers to health, and provide an adequate and effective defense against viruses and germs.

DISPOSITION: On 5-17-61, Pentron Sales Co., Inc., claimed the articles and denied that the articles were misbranded. On 5-18-61, the case was removed by stipulation to the Southern District of Illinois. On 5-27-63, the claimant withdrew its claim and answer by stipulation, and, on 6-4-63, a decree of condemnation and destruction was filed.

7417. Trion electronic air cleaner. (F.D.C. No. 47914. S. No. 11-934 T.)

QUANTITY: 4 individually ctn'd. devices at Buffalo, N.Y.

SHIPPED: Between 10-21-60 and 5-29-62, from McKees Rocks, Pa., by Trion, Inc.

LABEL IN PART: (Ctn.) "Trion Electronic Air Cleaner Type * * * Model No. * * * Serial No. * * * Trion, Inc. McKees Rocks, Pa."

ACCOMPANYING LABELING: Booklets entitled "The Automatic Housekeeper," "Trion Model TPF," and "Trionized Air For Your Home means . . ."

RESULTS OF INVESTIGATION: The device was an electrostatic precipitator-type air filter, consisting of ionizing wires, collector plates, a power supply and a water-wash spray system housed in a heavy steel cabinet.

LIBELED: 8-1-62, W. Dist. N.Y.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that use of the device would prevent lung cancer and other harm to the lungs; and reduce the germ content of the air 90 to 94 percent; that users of the device would lead more clean and healthful lives; and that victims of airborne allergies would be relieved of such allergies by use of the device; and that the device extracted virtually all pollen, dust, dirt, smoke and other airborne particles from the air.

DISPOSITION: 3-20-63. Consent—claimed by Trion, Inc., and ordered released under bond for relabeling.

7418. Vivicosmic Disc, Radiant Life Meter, and Household Analysis Sets. (F.D.C. No. 48120. S. No. 32-482 T.)

QUANTITY: 400 1-gal. size, 10 5-gal. size, and 40 2-gal. size boxed discs, 10 unlabeled *Radiant Life Meters*, and 8 unlabeled boxes of *Household Analysis Sets*, at Northridge, Calif.

SHIPPED: On unknown date and between 1-15-62 and 2-14-62, from Tumtum, Wash., by Radiant Laboratories.

LABEL IN PART: (Box) "Herb Blackschleger's Vivicosmic Disc Sold only for experimental use by ESP and Metaphysical Enthusiasts The Living Essence * * * The enclosed Vivicosmic Disc contains: Organic Cereals and Mineral Elements Natural Organic Positive Yeast Phyballooomm Psyterra and the blessings of Herb Blackschleger. Directions for Use: * * * Modern Science is rather uninformed in matters pertaining to the Divine Mind and Divine Healing. The contents of this package can increase the harmonious inter-relationship thereof. Packed by Dominion-American Corporation, P. O. Box 188 Sun Valley, Calif. Licensed by Radiant Labs., Tum Tum, Wash."

ACCOMPANYING LABELING: Leaflets entitled "Analysis Summary," "U.S.A. Producers Distributors & Dealers Nation Wide," and "Judge Not According to Appearance Judge Right—Use Judgement (No. 12)," "Welcome 2d edition Lesson 1 & 2 page 1," "Radiant Vitagrower," "Radiant Grahamizing Instructions," "Learn Your Sixth Sense," "Herb's Occasional Letter" ("Mid-Year AK 113," "Late Summer AK 113," "Winter AK 113-4 (1961-2),"

"Spring AK 114 (1962)," and "Summer, AK 114 (1962)"), "We are pleased to announce: The Radiant Vita Grower," and "How To Test Your Vivicosmic Disc."

RESULTS OF INVESTIGATION: The *Vivicosmic Disc* was a porous, molded disc of dried mud of various diameters and thicknesses intended to contain bacteria.

The *Radiant Life Meter* was a small handle which was suspended by a small beaded strip of metal, folded in U-shape; the rotation of the pendulum determined the polarity or activity of a product.

Each box of the *Household Analysis Set* contained 1 *Radiant Life Meter*, 1 6-ply piece of wood, $5\frac{1}{2}'' \times 2\frac{5}{8}''$, each piece containing 18 holes, bearing a number as "52" or "54" or other numbers not in sequence up to 108, and each hole contained 1 corked glass vial not removable. One of each of the first 3 leaflets described above was wrapped around each box. Some of the leaflets were shipped by Radiant Laboratories and some were prepared locally by the dealer, Herb Blackschleger.

LIBELED: 9-28-62, S. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling contained false and misleading representations that the *Radiant Life Meter* and the *Household Analysis Set* had value and were useful in the detection of toxins, radiation, poisons, fallout, pesticides, and the absence of needed elements of the body in man, animal, fowls, soils, plants, food, and water which cause sickness, sterility, insanity, loss of vitality, health, happiness, and other conditions; and that water treated with the *Vivicosmic Disc* was adequate and effective for reducing abscesses, removing pesticides, fallout, and radiation contamination from fruits and vegetables; calming the nerves; preventing tiredness, pain, tooth decay, and galling of the armpits; improving the complexion; and causing pregnancy to be more pleasant.

DISPOSITION: 12-21-62. Default—delivered to the Food and Drug Administration.

7419. Vibrator device. (F.D.C. No. 48580. S. Nos. 31-348/50 V.)

QUANTITY: 2,400 individually ctnd. devices at Los Angeles, Calif., in possession of Allied Liquidators.

SHIPPED: Between 5-11-62 and 5-18-62, from Muskogee, Okla.

LABEL IN PART: (Metal plate on device) "Home Therapy Model * * * Beau Monde Mfg. Co. * * * Levelland, Texas."

ACCOMPANYING LABELING: Leaflets entitled, "For Men and Women of All Ages" and "Beau-Monde Vibrators Positions And Uses As Illustrated."

RESULTS OF INVESTIGATION: Examination of the article showed it to be a fabric pad, tapered at one end with the dimension of $15'' \times 2'' \times 2\frac{1}{2}'$, attached to a plastic frame of the same size. A green plastic box (containing the vibrator unit) was attached to the frame. The box had an electric outlet cord. Two accessories, a green plastic footrest and a V-shaped pillow on a plastic frame, were included.

The dealer had on hand the above leaflets, which were used in promoting sales of the device.

LIBELED: 1-10-63, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the accompanying labeling contained representations that the article was an adequate and effective treatment for relieving arthritis, back discomfort, sinus conditions, and poor circulation.

DISPOSITION: 2-25-63. Consent—claimed by Allied Liquidators & Associates, Inc., and relabeled.

DRUGS FOR VETERINARY USE*

7420. Veterinary drugs. (Inj. No. 365.)

COMPLAINT FOR INJUNCTION FILED: 12-2-59, Dist. Md., against Amos D. Burhans, t/a Burhans Veterinary Remedy Co., Annapolis, Md.

CHARGE: The complaint alleged that the defendant was manufacturing, packing, selling, and distributing in interstate commerce, articles of drug intended for use by dogs and designated by the names "*Burhans' Distemper Treatment*," "*Breeder Stimulator Tablets*," "*Burhans' Whelping Compound*," "*Burhans' Brood Matron Breeding Mixture*," "*Brood Matron Blood Cleanser*," "*Garlico Condition Powder*," and "*Internal Blood Cleansing Skin Tonix Tablets*"; that the ingredients of such drugs were as follows: *Burhans' Distemper Treatment*—potassium, dichromate beechwood creosote, and calcium iodide; *Breeder Stimulator Tablets*—nux vomica, extract damiana, strychnine, cantharides, orchic substance, and zinc phosphide; *Burhans' Whelping Compound*—Ergotin Bonjean, extract of cotton root, extract of black hellebore, aloes, ferrous sulfate, and savin oil; *Burhans' Brood Matron Breeding Mixture*—feeding yeast, wheat germ, milk minerals, milk sugar, lactose, and calcium phosphate, Di-basic; *Brood Matron Blood Cleanser*—calcium iodized, iodine, and sulfur; *Garlico Condition Powder*—ferrous sulfate, powdered charcoal, sodium bicarbonate, precipitated sulfur, magnesium sulfate, a bitters, and powdered garlic and/or onion; *Internal Blood Cleansing Skin Tonix Tablets*—sulfur, potassium bitartrate, ipecac, capsicum, arsenous acid, and calcium sulfide; and that the drugs, when sold and distributed in interstate commerce, were misbranded as follows:

502(a)—the labeling of the drugs which included the names of the drugs, the container labels and an accompanying booklet entitled "*Burhans 1959-1960 Dog Book*" contained the following false and misleading representations with respect to the use of such drugs for dogs: (1) that *Burhans' Distemper Treatment* was an adequate and effective treatment for distemper, all fever conditions caused by digestive disturbances, bowel troubles, blacktongue, German distemper, walking distemper, colds, ordinary infections, diarrhea, dysentery, gastroenteritis, kennel flu, coughing, dog-show fever, shipping fever, pneumonia, and respiratory and stomach conditions, and that the drug was adequate and effective for use as an anthelmintic for dogs; (2) that the *Breeder Stimulator Tablets* would stimulate breeding and breeding activity and increase fertility; (3) that *Burhans' Whelping Compound* was an adequate and effective treatment for slow whelping and hard whelping females, for shrinking and contracting the horns of the uterus, and for expelling puppies and after-birth; (4) that *Burhans' Brood Matron Breeding Mixture* was an adequate and effective treatment for breeding purposes, for producing perfect litters, and for stimulating a good milk supply; (5) that the *Brood Matron Blood Cleanser* was an adequate and effective treatment for cleansing the blood and destroying worm larvae; (6) that the *Garlico Condition Powder* was an adequate and

*See also Nos. 7380, 7390.

effective treatment for promoting digestion, expelling worms, cleansing the system of poisons, sweetening the breath, and acting as a stomach and intestinal sweetener or antacid, an internal antiseptic for puppies, or as a parasite detergent; and (7) that the *Internal Blood Cleansing Skin Tonix Tablets* were an adequate and effective treatment for cleansing the blood, treating the skin, treating skin troubles that originate in the blood, relieving pustular discharge on the body and toes, all forms of eczema, dry scaly skin, harsh-looking coat, and killing offensive skin odors;

502(b) (2)—all of the articles failed to bear statements of the quantity of contents;

502(b) (1)—the *Breeder Stimulator Tablets*, *Brood Matron Blood Cleanser*, and *Internal Blood Cleansing Skin Tonix Tablets* failed to bear labels containing the correct place of business of the manufacturer, packer, or distributor;

502(e) (2)—the *Breeder Stimulator Tablets* were fabricated from two or more ingredients and their label failed to bear the name and quantity or proportion of strychnine contained in the tablets.

The complaint alleged further that if the defendant was merely restrained from introducing into interstate commerce, any of the drugs with false and misleading labeling, the defendant would not discontinue interstate distribution of the drugs but would continue to ship the drugs in interstate commerce without specifying in their labeling the purposes and conditions for which the drugs were intended. In such case the drugs would be misbranded under 502(f) (1) in that their labeling would not bear adequate directions for use because of the omission from their labeling of the purposes and conditions for which the drugs were to be used.

The complaint alleged also that the defendant had been warned on various occasions by the Food and Drug Administration that his drugs were misbranded as the result of false and misleading labeling; that such warnings had been given at factory inspections on 11-18-47, 12-11-53, and 1-30-59; in a letter dated 1-21-48; and by notices of hearing issued on 9-20-54 and 5-22-59; and that in spite of such warnings the defendant continued to introduce misbranded drugs into interstate commerce.

DISPOSITION: The defendant, having failed to answer the complaint or to appear, on 1-8-60, at the hearing on the Government's motion for preliminary injunction and the court having considered the affidavits and testimony of the Government's witnesses, a preliminary injunction was entered, on 1-22-60, enjoining the defendant against introducing into interstate commerce the above-named drugs or any articles of similar composition which (a) bear or are accompanied by written, printed, or graphic matter in which such articles are designated by the names "*Burhans' Distemper Treatment*," "*Breeder Stimulator Tablets*," "*Burhans' Whelping Compound*," "*Burhans' Brood Matron Breeding Mixture*," "*Brood Matron Blood Cleanser*," "*Garlico Condition Powder*," and "*Internal Blood Cleansing Skin Tonix Tablets*"; (b) are accompanied by the booklet entitled "*Burhans' 1959-1960 Dog Book*" or by any written, printed, or graphic matter substantially to the same effect; (c) bear or are accompanied by written, printed, or graphic matter which contain the above-mentioned false and misleading representations with respect to the articles; (d) fail to bear labels containing the correct address of the manufacturer, packer, or distributor of such articles, and accurate statements of the quantity of contents of such articles; (e) fail to bear labeling stating every disease, condition, symptom, and purpose for which such articles are

intended to be used and for which they are represented by any means to the public; or (f) fail to bear, in the case of the drug known as "*Breeding Stimulator Tablets*," a label containing the name and quantity or proportion of strychnine contained in the article.

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Rheumatism, remedies for.		lets, Cookies, and Reducing	
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Breeder Stimulator Tablets.....	² 7420	Tonix Tablets.....	² 7420
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Crysto-Vim 12 injection.....	7393	Lumbago, remedies for. <i>See</i>	
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Foot remedy.....	7410	ing preparations.	

¹(7396, 7401, 7412, 7414, 7416) Seizure contested.

²(7361, 7408, 7413, 7420) Injunction issued.

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A-Gic Laboratories, Inc.:		Blackschleger, Herb:	
A-Gic Jel-----	7411	Vivicosmic Disc, Radiant Life	
Allied Liquidators:		Meter, and Household Analy-	
vibrator device-----	7419	sis Sets-----	7418
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Archer-Taylor Drug Co.:		veterinary drugs-----	² 7420
Crysto-Vim 12 injection-----	7393	Burhans Veterinary Remedy Co.	
Balanced Foods, Inc.:		<i>See</i> Burhans, A. D.	
various safflower oil and gluten		Canfield, C. R., & Co.:	
products -----	¹ 7401	'BST'-SOL injections-----	¹ 7412
Banner Gelatin Products Corp.:		Chemical Commodities, Inc.:	
safflower oil perles-----	7400	Dr. Reeves' Special Foot	
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Bender, Dr. Austin:		Verv capsules-----	7373
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¹(7396, 7401, 7412, 7414, 7416) Seizure contested.²(7361, 7408, 7413, 7420) Injunction issued.³(7391) Seizure contested. Contains opinions of the court, consent decree of condemnation and injunction.

	N.J. No.		N.J. No.
Cook, K. E., D.C.:		Hartz, The, Co.:	
Bioelectrometer device-----	7379	vitamin B ₁ tablets and niacin tablets-----	¹ 7396
Cornell Instrument Co., Inc.:		Healthway Food Center:	
clinical thermometers-----	7386	safflower oil products-----	7400
Davis-Edwards P h a r m a c a l Corp.:		Hoffman, Bob:	
Pac-A-Dex timed disintegration capsules-----	7366	Hoffman's Super Hi-Proteen tablets, Cookies and Reducing Aid tablets-----	7385
de Vore, A. F.:		Hostetter, Mrs. Penny:	
Glyoxylide injection-----	7380	Nutri-Bio food supplements---	7397
Dietetic Food Co., Inc.:		Ipcó Hospital Supply Corp.:	
gluten products-----	¹ 7401	clinical thermometers-----	7387
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Specifex A d r e n a l Hormone Cream-----	² 7408	Oral Hydrosulphosol-----	² 7361
Etherton, M. C.:		Lientz, E. C., & Co., Inc.:	
Specifex A d r e n a l Hormone Cream-----	² 7408	Oral Hydrosulphosol-----	² 7361
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safflower all vegetable spread_	7400	rubber prophylactics-----	7388
Harper Laboratories, Inc.:			
Amovit tablets-----	7394		

¹(7396, 7401, 7412, 7414, 7416) Seizure contested.²(7361, 7408, 7413, 7420) Injunction issued.

	N.J. No.		N.J. No.
Martin's Service :		Professional Veterinary Drug	
Lix-Pain cream liniment-----	7409	Co. :	
National Lecithin, Inc. :		'BST'-SOL injections-----	¹ 7412
Lecitabs (lecithin tablets)-----	7402	Radiant Laboratories :	
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disintegration tablets, and		ride tablets-----	7372
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Sytobex cyanocobalamin injec-		Selectronair air purifier device_	¹ 7414
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Pauls, P. D., D.O. :		vegetable margarine-----	7400
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Professional Dietary Quotas Co. :			
safflower oil capsules-----	7399		

¹(7396, 7401, 7412, 7414, 7416) Seizure contested.²(7361, 7408, 7413, 7420) Injunction issued.³(7391) Seizure contested. Contains opinions of the court, consent decree of condemnation and injunction.

	N.J. No.		N.J. No.
Van Stone, L. F. :		Walnut Acres :	
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Visible Spectrum Research Insti-		tablets and capsules-----	7395
tute :		Wayne Drug Co., Inc. :	
Visible Spectrum Color Pro-		cyanocobalamin injection-----	7392
jector -----	² 7413	York Barbell Co. :	
Vitamin Council, Inc. :		Hoffman's Super Hi-Proteen	
safflower oil capsules-----	7399	tablets, Cookies, and Reduc-	
		ing Aid tablets-----	7385

²(7361, 7408, 7413, 7420) Injunction issued.

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U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

7421-7460

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were alleged to be adulterated or misbranded, or otherwise violative of the Act, when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent, and (2) a criminal proceeding which was terminated upon a plea of guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceeding is against the *firm* charged to be responsible for the violation.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., April 21, 1964.

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*For omission of, or unsatisfactory, ingredients statements, see Nos. 7423, 7448; failure to bear a label containing an accurate statement of the quantity of the contents, No. 7423; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 7423, 7443; cosmetic, under the drug provisions of the Act, No. 7458.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D.D.N.J. NOS. 7421-7460

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (National Formulary), and its quality fell below the standard set forth in such compendium.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2) in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient contained therein; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUGS FOR HUMAN USE

7421. Amphetamine compound timed disintegration capsules. (F.D.C. No. 47784. S. No. 64-830 T.)

QUANTITY: 21,800 capsules in bulk drum at Huntington Park, Calif.

SHIPPED: 4-13-62, from Philadelphia, Pa., by Philadelphia Laboratories, Inc.

LABEL IN PART: (Drum) "Amphetamine Compound No. 30 (Timed Disintegration Capsule) Each Capsule Contains: Amphetamine Sulfate 30 mg. Thyroid 3 Gr. Aloin $\frac{1}{4}$ Gr. Atropine Sulfate $\frac{1}{180}$ Gr. Phenobarbital $\frac{1}{4}$ Gr. * * * Philadelphia Ampoule Laboratories, Philadelphia 23, Pa."

LIBELED: 6-28-62, S. Dist. Calif.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since an application filed pursuant to 505(b) was not effective with respect to such drug.

DISPOSITION: 8-21-62. Default—destruction.

7422. Anti-Coagulant and KC 555. (F.D.C. No. 47160. S. Nos. 6-076/7 T.)

QUANTITY: 1 btl., containing approximately 1 gal. of *Anti-Coagulant*, at Hartford, Conn., and 6 8-oz. btls. of *KC 555*, at New Haven, Conn.

SHIPPED: Between 10-1-61 and 11-26-61, from Englewood Cliffs, N.J., by Kegan Sarkisian, t/a Kegan Research Laboratory, Inc.

LABEL IN PART: (Btl.) "Anti-Coagulant. New Drug Limited by Federal Law to investigating use. Prepared by Kegan Research Lab. Englewood, N.J." and (btl.) "KC 555 a botanical extract derived from Asian-grown plants, it is used as an adjunctive treatment in malignant diseases, and as a stimulant when you feel run-down or listless. Contains: * * * and KC 555 preparation. Prepared by Kegan Research Laboratory, Inc., Englewood Cliffs, New Jersey."

RESULTS OF INVESTIGATION: The article, *Anti-Coagulant*, was prepared in Connecticut by adding sherry wine to the *Anti-Coagulant* base which had been shipped in interstate commerce as shown above. The article, *KC 555*, was prepared in Connecticut by adding Chianti and Fernet Branca wines to quantities of *KC 555* which had been shipped in interstate commerce, and, subsequently, the combined article was redelivered within the state.

LIBELED: 3-1-62, Dist. Conn.

CHARGE: 505(a)—the articles were new drugs which may not be introduced or delivered for introduction into interstate commerce, since an application filed pursuant to 505(b) was not effective with respect to such drugs.

DISPOSITION: 9-20-62. Default—destruction.

7423. Diethylstilbestrol tablets. (F.D.C. No. 47137. S. No. 6-842 T.)

QUANTITY: One unlabeled btl., containing 10,000 tablets, and one unlabeled btl., containing 6,250 tablets, at Griswold, Conn.

SHIPPED: The article was delivered to the dealer at Griswold, Conn., by David Cramer, Cromwell, Conn., after having received the article from the New Holland Supply, Inc., New Holland, Pa.

LIBELED: 2-24-62, Dist. Conn.

CHARGE: 502(b)—while held for sale, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents; 502(e) (1)—the label of the article failed to bear the common or usual name of the article; 502(f) (1)—the labeling of the article failed to bear any directions for use; and 505(a)—the article was a new drug within the meaning of the law and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: 9-19-62. Default—destruction.

7424. Covatrate '80' Timekaps. (F.D.C. No. 47484. S. No. 24-342 T.)

QUANTITY: 13,000 capsules, in btl. of 100, 500, and 1,000 capsules, at Mansfield, Ohio.

SHIPPED: 2-6-62, from St. Louis, Mo., by Shaw Pharmacal Co.

LABEL IN PART: (Btl.) "Covatrate '80' Timekaps * * * Each Capsule contains Pentaerythritol Tetranitrate 80 mg. in a timed disintegration base that provides for disintegration of the contents over a period of 6-8 hours * * * Distributed by the Caldwell & Bloor Company, Mansfield, Ohio."

RESULTS OF INVESTIGATION: The capsules were repacked into bottles from bulk drums shipped as described above.

LIBELED: 5-24-62, N. Dist. Ohio.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since an application filed pursuant to 505(b) was not effective with respect to such drug.

DISPOSITION: 8-9-62. Default—destruction.

DRUG FOR VETERINARY USE

7425. Sodium selenite injection "BO-SE" and "LE-SE" (veterinary). (F.D.C. No. 47624. S. Nos. 62-931/2 T.)

QUANTITY: 30 30-cc. vials of "BO-SE" and 15 30-cc. vials of "L-SE" at Minneapolis, Minn.,

SHIPPED: 2-6-62 and 3-1-62, from Oakland, Calif., by H. C. Burns Co., Inc.

LABEL IN PART: (Vial) "For The Prevention And Treatment Of White Muscle Disease (Myopathy) Each cc contains: Selenium * * * Vitamin E * * * Thimerosal * * * Polysorbate 80 USP * * * Water for injection qs. Manufactured For H. C. Burns Co., Inc., Oakland, California."

ACCOMPANYING LABELING: Copies of printed material reading in part "Extract White Muscle Disease by C. C. Beck, D.V.M.," (on H. C. Burns Co. letter-head) "Telephone Conversation Between B. D. Kuhl, D.V.M., Baker, Oregon, and George McConnell," "Technical Bulletin No. 6," "Joint-Ill in Hogs," "State of California Department of Agriculture Inter-Office Memo," and "A Preliminary Report On The Use of BO-SE For Retained Placenta."

LIBELED: 6-1-62, Dist. Minn.

CHARGE: 502(a)—when shipped, the labeling accompanying the articles contained false and misleading representations that the articles were adequate and effective as a treatment for retained placenta and knuckler's disease in cattle, and joint ill in swine; 502(f) (1)—the labeling failed to bear adequate directions for use and the articles were not exempt from that requirement, since the promotional material for the articles was not the same as, or substantially the same as, the labeling authorized by the effective new drug application filed with respect to the articles; and 505(a)—the articles were new drugs which may not be introduced into interstate commerce, and the new drug application filed with respect to the articles did not apply to the conditions described above for which the articles were represented in their accompanying labeling.

DISPOSITION: 7-17-62. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

7426. PABA tablets. (F.D.C. No. 46966. S. Nos. 28-223 T, 28-229 T.)

QUANTITY: 1 48, 700-tablet drum at Overland Park, Kans.

SHIPPED: 6-6-60, from St. Louis, Mo., by Shaw Pharmacal Co.

LABEL IN PART: (Drum) "Lot: 12069 Shaw St. Louis Date 6/6/60 C.T. PABA 0.5 gram tablets * * * Each tablet contains: Para Aminobenzoic Acid 0.5 gram * * * Manufactured by Shaw Pharmacal Co. * * * St. Louis, Mo."

RESULTS OF INVESTIGATION: Analysis showed that the article failed to meet the requirements of the National Formulary, an official compendium, for tablet-weight variation and tablet disintegration.

LIBELED: 2-8-62, Dist. Kans.

CHARGE: 501(b)—when shipped, the article purported to be a drug, para-aminobenzoic acid tablets, the name of which is recognized in the National Formulary, an official compendium, and its quality fell below the standard with respect to tablet-weight variation and tablet disintegration as set forth in such compendium; 502(a)—the label statements "PABA 0.5 gram tablets" and "Each tablet contains: Para Aminobenzoic Acid 0.5 gram" were false and mis-

leading as applied to a product which did not conform to the requirements of the National Formulary; and 503(b)(4)—the article was a drug subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 5-29-62. Default—destruction.

7427. Vermazine piperazine citrate syrup. (F.D.C. No. 47660. S. No. 64-593 T.)

QUANTITY: 25 cases, 12 4-oz. jars each, at Atlanta, Ga.

SHIPPED: 3-26-62, from Miami, Fla., by Barry-Martin & Co.

LABEL IN PART: (Jar) "Vermazine Piperazine Citrate Syrup * * * Barry-Martin & Co. Distributor Miami, Fla. Each cc contains 100 mg. of piperazine citrate, equivalent to 90 mg. of piperazine hexahydrate."

LIBELED: 6-6-62, N. Dist. Ga.

CHARGE: 503(b)(4)—when shipped, the article was a drug subject to 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 7-16-62. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

7428. Amphetamine sulfate tablets. (F.D.C. No. 48110. S. No. 84-321 T.)

QUANTITY: 1,500,000 tablets in possession of Shannon High, at East Prairie, Mo.

SHIPPED: Prior to 8-22-62, a quantity of bulk amphetamine powder was shipped from outside the State of Missouri, to St. Louis, Mo., where it was used in the manufacture of *amphetamine sulfate tablets*, which were subsequently delivered to East Prairie, Mo.

LIBELED: On or about 8-31-62, E. Dist. Mo.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use, and the article was not exempt from such requirement since it was not intended to be dispensed upon prescription.

DISPOSITION: 1-23-63. Default—destruction of 46 tablets, which was the amount actually seized.

7429. Prescription drugs. (F.D.C. No. 47723. S. Nos. 57-444/56 T, 70-937/8 T.)

QUANTITY: Various articles of drugs consisting of unknown quantities of *penicillin tablets*, *Orinase tablets*, *Sulfid B-A tablets*, *Desoid tablets*, *methyltestosterone tablets*, *desoxyephedrine hydrochloride tablets*, and unknown quantities of other prescription-type drugs, at Salina, Okla., in possession of James A. Nolen, t/a Radium Springs Sanitorium.

SHIPPED: On unknown dates, from outside the State of Oklahoma.

LIBELED: On or about 7-26-62, N. Dist. Okla.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use, and the articles were not exempt from such requirement since they were in the possession of a person who was not regularly and lawfully engaged in the manufacture, transportation, storage, wholesale distribution, or dispensing of prescription drugs, and since the articles were not to be dispensed upon prescription as required by 503(b).

*See also Nos. 7423, 7425.

DISPOSITION: 1-21-63. Consent—claimed by Dr. J. A. Liner. A portion of the articles which could be brought into compliance with the law were released to the claimant and the remainder of the articles were destroyed.

7430. Amphetamine sulfate tablets. (F.D.C. No. 48082. S. No. 84-322 T.)

QUANTITY: 510,000 tablets at Hayti, Mo., in possession of Levi D. Denton.

SHIPPED: Prior to 8-22-62, from Knoxville, Tenn.

LIBELED: 8-31-62, E. Dist. Mo.

CHARGE: 502(f) (1)—while held for sale, the labeling of the article failed to bear adequate directions for use, and the article was not exempt from such requirement since it was not intended to be dispensed on prescription as required by regulations.

DISPOSITION: 1-23-63. Default—5,000 tablets delivered to the Food and Drug Administration and the remainder destroyed.

7431. Various drugs. (F.D.C. No. 47691. S. No. 481 T.)

QUANTITY: Unknown number of tablets, capsules, and vials of *tranquilizers*, *barbiturates*, *antibiotics*, and other drugs at Rochelle, Ga., in possession of Ronald G. Shawver.

SHIPPED: On unknown dates, from outside the State of Georgia.

LIBELED: 6-11-62, M. Dist. Ga.

CHARGE: 502(f) (1)—the labeling of the articles failed to bear adequate directions for use, and they were not exempt from that requirement.

DISPOSITION: 1-21-63. Default—destruction.

7432. Turpentine. (F.D.C. No. 48224. S. No. 15-879 T.)

QUANTITY: 5 55-gal. drums, 77 cases, each containing 12 8-oz. btls., and 121 cases, each containing 12 3-oz. btls., at Terre Haute, Ind., in possession of Hulman & Co.

SHIPPED: 8-4-61 and 8-12-61, from Jacksonville, Fla.

LABEL IN PART: (Btl.) "Farmers Pride Brand Turpentine [or "Hulco Turpentine"] For Medicinal Purposes Made from Pure Gum Spirits Put Up By Hulman & Co. Terre Haute, Ind."

RESULTS OF INVESTIGATION: The article was shipped in bulk drums and repacked and labeled by the dealer, who also had additional repack labels on hand.

LIBELED: 10-17-62, S. Dist. Ind.

CHARGE: 502(f)—while held for sale, the labeling of the article (bulk and repack) failed to bear (1) adequate directions for use, and (2) a statement warning not to apply the article to irritated skin, or if excessive irritation develops, and to avoid getting it into the eyes or on mucous membranes, and that the product should be kept out of the reach of children.

DISPOSITION: 12-13-62. Consent—claimed by Hulman & Co. Previously unopened drums were returned to the supplier and the portion which had been bottled was returned to the bulk containers for use in maintenance. All bottles and labels were destroyed.

7433. Micro-Dynameter devices (2 seizure actions). F.D.C. Nos. 47950, 47984. S. Nos. 17-199 T, 72-481 T.)

QUANTITY: 2 devices, at Lexington and Raceland, Ky.

SHIPPED: Between 3-1-54 and 3-31-58, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "For Scientific Body Analysis The Ellis Micro-Dynamometer Mfd. by Ellis Research Laboratories, Inc., Chicago U.S.A."

ACCOMPANYING LABELING: Various pieces of literature pertaining to the devices.

RESULTS OF INVESTIGATION: Examination indicated that the devices were essentially galvanometers for measuring electrical currents and electrical potentials of small magnitude. Each device was mounted in a metal cabinet, on the face of which was a scale or meter intended to measure the flow of current in milliamperes, together with a number of dials which could be set at numbered or lettered positions. The dial settings were intended to increase or decrease the resistance to the current flowing through the device. The current which flowed and was measured by the scale or meter was generated by closing the circuit between two dissimilar metal "probes." The circuit was closed by placing the "probes" at different points on the human body, by placing the "probes" together, or by immersing them in water.

LIBELED: 8-15-62; 8-16-62, libel amended 12-3-62; E. Dist. Ky.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for diagnosing disease; and 502(f) (1)—the labeling of the articles failed to bear adequate directions for use and they were not entitled to any exemption from that requirement.

DISPOSITION: 1-10-63, 1-16-63. Default—delivered to the Food and Drug Administration.

7434. Micro-Dynamometer devices and Neurolinometer devices. (F.D.C. No. 48019. S. Nos. 11-472/3 T, 11-475/6 T.)

QUANTITY: 2 *Micro-Dynamometer devices* at McKeesport, Pa.; 2 *Neurolinometer devices*, at Wilmerding, Pa.

SHIPPED: On unknown dates, from Cumberland, Wis., and Chicago, Ill., by Ellis Research Laboratories, Inc., and Toftness System.

LABEL IN PART: (Micro-Dynamometer) "For Scientific Body Analysis The Ellis Micro-Dynameter Mfd. by Ellis Research Laboratories, Inc. Chicago, U.S.A."; (Neurolinometer) "Neurolinometer Toftness System, Cumberland Wisconsin."

RESULTS OF INVESTIGATION: Investigation indicated that the *Neurolinometer* was a device housed in a black, suitcase-type container, about 15 inches long, 9¾ inches wide, and 5½ inches deep. The face of the device contained 8 knobs variously labeled in part "ten," "one," "cervical," or "base." The device otherwise consisted of a monopolar electrode, a single-stage amplifier, and a power supply unit, the output of which was applied to a section of wire mesh attached beneath a sheet of bakelite.

LIBELED: 9-10-62, W. Dist. Pa.

CHARGE: 502(f) (1)—when shipped, the labeling of the articles failed to bear adequate directions for use for the purpose for which they were intended, namely, for the diagnosis of disease in man, in that the articles were worthless for use for such purpose and adequate directions could not be given for the use of the articles for such purpose.

DISPOSITION: 10-1-62. Default—destruction.

7435. Magnetic bracelets. (F.D.C. No. 48229. S. No. 2-442 V.)

QUANTITY: 449 men's bracelets and 449 women's bracelets, at Miami, Fla., in possession of Max N. Lichy & Sons, t/a International Silk & Novelties Corp.

SHIPPED: 5-26-62 and 6-25-62, from Osaka, Japan.

LABEL IN PART: The word "Relax" on the silver-colored inner side of every other link of the women's bracelet.

RESULTS OF INVESTIGATION: Examination showed that the article was a metal expansion-type bracelet consisting of slightly magnetic links.

LIBELED: 10-18-62, S. Dist. Fla.

CHARGE: 502(f) (1)—while held for sale, the article was intended for use in benefiting the health of the user, and its labeling failed to bear adequate directions for use for such purpose, and it was not feasible to devise adequate directions for use since the article was not effective for the intended purpose.

DISPOSITION: 12-11-62. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS AND DEVICES FOR HUMAN USE*

7436. Meprobamate tablets. (F.D.C. No. 42476. S. Nos. 4-401 P, 35-395 P.)

INFORMATION FILED: 2-15-60, E. Dist. N.Y., against Hall Pharmacal Co., Inc., Brooklyn, N.Y.

SHIPPED: 4-24-58 and 5-6-58, from Brooklyn, N.Y., to Philadelphia, Pa., and Richmond, Va.

LABEL IN PART: (Drum) "Meprobamate Tablets 400 MGM. CAUTION: Federal Law Prohibits Dispensing Without a Prescription * * * FOR INVESTIGATIONAL AND EXPORT USE ONLY * * * Hall Pharmacal Co., Inc., New York, N. Y."

CHARGE: 502(a)—when shipped, the label statement on the drum "FOR INVESTIGATIONAL AND EXPORT USE ONLY" was false and misleading in that the drug was not for investigational and export use.

PLEA: Guilty.

DISPOSITION: 6-11-62. \$2,000 fine.

7437. Ellis Vivo-Tone. (F.D.C. No. 47740. S. Nos. 14-231/3 T.)

QUANTITY: 271 100-capsule btl.s. of a dietary supplement, 43 100-capsule btl.s. of lecithin, and 266 100-tablet btl.s. of alfalfa, at Chicago, Ill., in possession of Ellis Research Laboratories, Inc.

SHIPPED: 6-19-59 and 7-27-59, from Oak Park, Mich.

LABEL IN PART: (Btl.) "9 Ellis Vivo-Tone A Dietary Supplement * * * Essential Unsaturated Fatty Acids As Present in Safflower Oil Plus Vitamin B-6 * * * Control No. 45924 [or "10 Vivo-Tone * * * Lecithin with Safflower Oil * * * Control No. 2421" or "11 Ellis Vivo-Tone * * * Alfalfa 10 gr. Tablets * * * Control No. 3960"] Available only through doctors who provide Micro-Dynameter Analysis * * * Distributed by Ellis Research Labs., Inc., Chicago 11, Illinois."

ACCOMPANYING LABELING: Booklets entitled "An Introduction To Vivo-Tone, A research paper submitted for the exclusive use of Micro-Dynameter users."

RESULTS OF INVESTIGATION: The articles were shipped in bulk lots which were subsequently repacked by the dealer into bottles described above.

*See also No. 7433.

LIBELED: 7-26-62, N. Dist. Ill.

CHARGE: 502(a)—while held for sale, the labeling accompanying the articles contained false and misleading representations that the articles were an adequate and effective treatment for arthritis, asthma, bursitis, eczema, hayfever, hepatic congestion, leucorrhea, lumbago, nephritis, rheumatism, sciatica, and many other serious disease conditions.

The libel alleged also that the articles were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 9-10-62. Default—destruction.

7438. Hadacol capsules. (F.D.C. No. 48116. S. No. 57-063 T.)

QUANTITY: 28 25-capsule btls. and 22 50-capsule btls. at Harlingen, Tex.

SHIPPED: 11-16-59, from Memphis, Tenn., by Hadacol, Inc.

LABEL IN PART: (Btl.) "Hadacol * * * A Dietary Supplement Capsules A high-potency concentrate of vitamins and minerals * * * Hadacol, Inc. Distributors Lafayette, Louisiana Each Hadacol Capsule contains * * * Folic Acid, USP 0.25 mg. * * * Directions: Adults: * * * one to three Hadacol Capsules daily."

ACCOMPANYING LABELING: Leaflet entitled "New! Super Hadacol."

LIBELED: 9-28-62, S. Dist. Tex.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for the treatment and prevention of tiredness, constipation, headaches, grouchiness, washed-out appearance, wornout condition, iron deficiency anemia, and nervousness.

The article was alleged also to be adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 10-27-62. Default—destruction.

7439. Safflower oil capsules. (F.D.C. No. 47215. S. No. 54-327 T.)

QUANTITY: 2 100-capsule btls. and 26 250-capsule btls. at Detroit, Mich., in possession of Crowley-Milner & Co.

SHIPPED: 2-6-62 and 2-16-62, from New York, N.Y., by Moffett Drug Co., Inc.

LABEL IN PART: "Special Safflower Caps. with Vitamin B-6 distributors Moffett Drug Company, Inc., Fifth Avenue, New York, N.Y. * * * Provides supplemental essential unsaturated fatty acids."

ACCOMPANYING LABELING: Display sign reading in part "Safflower Oil Capsules to Burn Fat, newest concept of weight control developed by doctors."

RESULTS OF INVESTIGATION: The display card was printed by the dealer.

LIBELED: On or about 3-13-62, E. Dist. Mich.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the article was of significant value for special dietary supplementation by reason of the presence of safflower oil; and that the article was adequate and effective to burn fat and to control body weight.

DISPOSITION: 8-21-62. Default—destruction.

7440. Safflower oil capsules. (F.D.C. No. 48115. S. No. 57-064 T.)

QUANTITY: 135 42-capsule btls. and 43 84-capsule btls. at Harlingen, Tex.

SHIPPED: 3-19-62, from Newark, N.J., by Welton Laboratories, Inc.

LABEL IN PART: "Welton Safflower Oil with Vitamin B-6 * * * A dietary Supplement For Use With The Slim-Wel Reducing Program Packaged by Welton Laboratories, Inc., Newark 4, New Jersey."

ACCOMPANYING LABELING: Booklet entitled "Diet Guide" and window banners reading in part "Safflower Oil With Vitamin B-6."

LICENSED: 9-28-62, S. Dist. Tex.

CHARGE: 502(a)—when shipped, the label contained false and misleading representations that the article was of significant value for special dietary supplementation by reason of the presence of safflower oil; and that the article was adequate and effective to reduce and to control weight even though consuming thousands of calories daily without regard to the total caloric intake, and to lower cholesterol levels of the blood.

DISPOSITION: 10-27-62. Default—destruction.

7441. Over 40 vitamin and mineral tonic. (F.D.C. No. 47181. S. No. 29-496 T.)

QUANTITY: 216 display ctns., containing 1 4-oz. btl. and 1 8-oz. btl. each, at Kansas City, Mo., in possession of Over 40 Health Products Co.

SHIPPED: During October 1961, from New York, N.Y., by Vitarine Co., Inc.

LABEL IN PART: (Ctn.) "Over 40 Vitamin & Mineral Tonic Special Introductory Offer" and (btl.) "Over 40 Vitamin & Mineral Tonic Especially formulated For People 'Over 40' * * * Distributed by 'Over 40' Health Products Company, Kansas City, Missouri."

ACCOMPANYING LABELING: Leaflet entitled "If you are Over 40 . . . If you feel Weak and Tired . . . if you do not have the Energy you had when you were younger Over 40 Tonic is for you!"

RESULTS OF INVESTIGATION: The leaflets and cartons were prepared by the dealer.

LICENSED: 3-2-62, W. Dist. Mo.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the article was adequate and effective for the treatment and prevention of premature aging, weakness, tiredness, rundown condition, irritating symptoms, aches and pains, irregularity, digestive upset, irritability, insomnia, "half-alive" feeling, disease, listlessness, and for energy of youth; to build the blood, good health, and vitality; to feel, look, and sleep better; that the article was a vitamin and mineral tonic; that the nutritional requirements of the elderly are different from those of adults, generally; that 90 milligrams of iron must be consumed daily for adequate nutrition; and that three-fourths of the people are not getting the quality and quantity of food required to prevent vitamin and mineral shortages.

DISPOSITION: 7-16-62. Default—destruction.

7442. C-Tex vitamin C tablets. (F.D.C. No. 47434. S. Nos. 22-928/35 T.)

QUANTITY: 103 100-mg. btls. and 153 250-mg. btls. at Casper, Wyo.

SHIPPED: 2-16-62, from Berkeley, Calif., by Staynor Corp., on order of Adams Drug Brokerage (C-Tex Co.), Denver, Colo.

LABEL IN PART: (Btl.) "Tablets C-Tex Tasty Orange Flavored Vitamin C (ascorbic acid) 100 mg. [or "250 mg."] * * * distributed by Adams Drug Brokerage, Denver, Colo."

ACCOMPANYING LABELING: Leaflets entitled "Compliments of C-Tex" and "C-Tex Reach For. . ."

LIBELED: 4-9-62, Dist. Wyo.

CHARGE: 502(a)—when shipped, the labeling, namely, the leaflets entitled "Compliments of C-Tex" and "C-Tex Reach For. . ." accompanying the article, contained false and misleading representations that the article was adequate and effective for the treatment and prevention of alcoholism, anemia, cardiovascular disease, common cold, multiple sclerosis, peptic ulcer, hypertension, habitual abortion, and lack of alkaline reserve.

DISPOSITION: 5-25-62. Default—destruction.

7443. Dr. Durham's Tonic. (F.D.C. No. 48233. S. No. 77-349 T.)

QUANTITY: 13 1-gal. btls. at Atlanta, Ga., in possession of Walker H. Durham, M.D.

SHIPPED: 3-14-62, from Bristol, Tenn.

LABEL IN PART: (6-oz. btl.) "Dr. Durham's No. 1 Tonic and Stimulant to Appetite Active Ingredients: Triticum; Macrotys; Yellow-Root; Cascara Amarga; Sarsaparilla; Yellow Dock; Prickly Ash Bark; Stillingia; Phytolacca; Fringe Tree Bark * * * Indicated in Diseases of Blood, Liver, Stomach, and Kidneys. Directions for use * * * For Sale At Drug Stores Atlanta, Ga. * * * 6 fl. oz."

ACCOMPANYING LABELING: Placards entitled "Try a bottle of Dr. Durham's No. 1," "Do you need a Boost or Lift Up—Then try a bottle of Dr. Durham's No. 1. * * * Chronic Diseases of men and women," and "Dr. Durham's No. 1 A good reliable tonic * * * For your Health's Sake"; and a 3" by 5" card entitled "Try a Bottle of Dr. Durham's No. 1."

RESULTS OF INVESTIGATION: The article was shipped in the 1-gal. containers and in the normal course of the dealer's business operations was to be repacked into 6-oz. bottles and labeled as described above.

LIBELED: 10-10-62, N. Dist. Ga.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was a tonic, and an adequate and effective treatment for all diseases of blood, liver, kidneys, stomach, arthritis, and rheumatism, and other chronic diseases of men and women; and 502(b) (1)—the article failed to bear a label containing the distributors name and place of business.

DISPOSITION: 11-13-62. Default—destruction.

7444. Throck's R-6000 Formula. (F.D.C. No. 46239. S. No. 84-946 R.)

QUANTITY: 482 8-oz. btls. at Peoria, Ill., in possession of Peoria Drug Co.

SHIPPED: The raw materials were shipped between 10-1-60 and 11-22-60, from New York, N.Y., and St. Louis, Mo.

LABEL IN PART: "Throck's R-6000 Formula Concentrated. * * * Active ingredients: Bismuth Subgallate, Calcium Carbonate, Magnesium Carbonate, Potassium Bicarbonate, Sodium Bicarbonate, Essence Peppermint. Dosage * * * Manufactured by Peoria Drug Co., L. E. Throckmorton, R. Ph. G., * * * Peoria, Illinois."

ACCOMPANYING LABELING: Leaflet entitled "Throck's R-6000 Formula Anti-Acid Formula"; cards entitled "Throck's R-6000 Formula."

RESULTS OF INVESTIGATION: The article was manufactured by the dealer from raw material shipped in interstate commerce. The dealer had had the accompanying labeling printed locally.

LIBELED: 8-8-61, S. Dist. Ill.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was an adequate and effective treatment for ulcers of the intestinal tract, protected the irritated walls of the stomach, and stimulated digestion.

DISPOSITION: 9-20-62. Default—destruction.

7445. Reclu. (F.D.C. No. 46913. S. No. 48-578 T.)

QUANTITY: 4 cases, 12 16-oz. btls. each, and 7 cases, 12 8-oz. btls. each, at Pleasant Hill, Calif.

SHIPPED: Between 9-25-61 and 11-14-61, from Seattle, Wash., by Reclu Drug Co., Ltd.

LABEL IN PART: (Btl.) "Reclu * * * 1 Pint * * * Distributed by Reclu Drug Company, Ltd. 1931 Aurora Seattle 9, Washington Subsidiary of the Reclu Drug Company Ltd. Vancouver Canada Directions * * * Active Ingredients: Solution Sodium Citrate; Bismuth Subcarbonate; Tincture Gentian Compound; Compound Tincture Rhubarb; B.P."

ACCOMPANYING LABELING: Leaflet entitled "Acid Stomach? Try . . . Reclu Do you suffer from . . ."

LIBELED: 1-17-62, N. Dist. Calif.

CHARGE: 502(a)—when shipped, the name of the article, *Reclu* (ulcer spelled backwards), and the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for stomach ulcers.

DISPOSITION: 7-18-62. Default—destruction.

7446. Antacid gastric sedative. (F. D. C. No. 47445. S. No. 55-142 T.)

QUANTITY: 17 cases, 12 btls. each, at Albany, Ga.

SHIPPED: 10-24-61, from Greenville, S.C.

LABEL IN PART: (Btl.) "Engram's S-R For Stomach Relief Antacid Gastric Sedative. * * * Active Ingredients: Cerium Oxalate, Bismuth, Oxycarbonate, Calcined Magnesia, Sodium Bicarbonate, Oil of Peppermint, Net Wt. 4 ozs. Distributed by S-R Company * * * Albany, Georgia."

RESULTS OF INVESTIGATION: The article was formulated by the S-R Co., Albany, Ga., and manufactured and packed for such firm at Greenville, S.C. Labels for the article were supplied to the manufacturer by such firm.

LIBELED: 4-13-62, M. Dist. Ga.

CHARGE: 502(a)—when shipped, the label of the article contained false and misleading representations that the article was adequate and effective as a treatment for gas, inflammation, acid disturbances, nausea, and ulcerated stomach and intestines; and 502(e) (2) the label of the article failed to bear the common or usual name of each active ingredient, since oxycarbonate is not the common or usual name of the ingredient so designated.

DISPOSITION: 7-6-62. Default—destruction.

7447. Batherapy. (F.D.C. No. 47965. S. No. 64-733 T.)

QUANTITY: 1,078 2-oz. ctns., 40 1-lb. ctns., and 16 2-lb. ctns., at Los Angeles, Calif., in possession of Vitamin-Quota.

SHIPPED: Between 1-24-62 and 7-11-62, from New York, N.Y., by Vitamin-Quota.

LABEL IN PART: (Ctn.) "A Doctor's Discovery * * * Bathe Away Arthritic and Rheumatic-Like Aches and Pains* Batherapy * * * Temporary Relief. Dist. by General Therapeutics, Inc., 37 W. 26th St., N.Y., 10, N.Y. * * * A Doctor's Formula Therma-Mineral Bath."

ACCOMPANYING LABELING: Package insert "How To Use Batherapy"; leaflets entitled "Top-Quality Health and Beauty Aids" and "Vitamin-Quota's Breath-Taking Mid-Summer Sale Savings."

LIBELED: 8-15-62, S. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for all pains of arthritis and rheumatism, body fatigue, tired, swollen and aching feet, athletic aches and pains, and insomnia and nervous tension.

DISPOSITION: 9-17-62. Default—destruction.

7448. Sea Brine. (F.D.C. No. 47630. S. No. 74-969 T.)

QUANTITY: 180 8-oz. btls. at Hayward, Calif.

SHIPPED: Between 10-1-61 and 12-31-61, from Lakeland, Fla., by Florida Sea Brine Laboratories, Inc.

LABEL IN PART: (Some btls.) "Sea Brine * * * Concentrated and bottled by Florida Sea Brine Laboratories, Inc. * * * Lakeland, Florida" (rubber stamped on label "U.S. Court Approved Label" on all but 12 bottles) and (some btls.) "Natural Sea Water * * * Sea Brine Brand Seasoning * * * Concentrated and bottled by Florida Sea Brine Laboratories, Inc."

ACCOMPANYING LABELING: Leaflets entitled "Sea Brine . . . from ocean to you."

LIBELED: 6-5-62, N. Dist. Calif.

CHARGE: 502(a)—when shipped, the label statement "U.S. Court Approved Label" was false and misleading in that it suggested and implied that the article had been approved and endorsed by the United States Courts, whereas such suggestion and implication were contrary to fact; and the labeling accompanying the article contained false and misleading representations that the article was of significant value, by reason of its iodine content, for special dietary and therapeutic use for promoting the activity of the thyroid gland and the production of the hormone, thyroxin.

DISPOSITION: 7-18-62. Default—a portion delivered to the Food and Drug Administration, and remainder destroyed.

7449. Yerba maté. (F.D.C. No. 45091. S. Nos. 37-312/13 R.)

QUANTITY: 82 ctns., 20 pkgs. of 30 bags each, 6 ctns., 116 pkgs. of 20 bags each, and 16 50-lb. chests, at Philadelphia and Bristol, Pa., in possession of Frederick Goldman.

SHIPPED: 6-14-60, from Brazil.

LABEL IN PART: (Ctn.) "Cassera Brand South American Maté" and (chest) "Made in Brazil * * * Erva Maté Do Brazil * * * Philadelphia Via New York."

ACCOMPANYING LABELING: Folders entitled "The Wonderful Story of Yerba Maté" and "Cassara Brand South America Maté"; leaflets entitled "A Good Suggestion."

LIBELED: 11-10-60, E. Dist. Pa.

CHARGE: 502(a)—while held for sale, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for producing exhilaration and relief from fatigue, stomach acidity, indigestion and constipation; was a heart tonic; a diuretic; exciting the brain to increased mental activity and capacity; stimulating organs of nutrition; comforting the mind and dispelling weariness, insomnia, cerebral erethism, headache, migraines, other cephalalgias, debility of neurasthenia, migraine, and dyspepsia; counteracting depression of alcoholic debauching, gout, stomach disorders, and nerve disorders.

DISPOSITION: 8-15-62. Default—destruction.

7450. Oral solution. (F.D.C. No. 47414. S. No. 66-002 T.)

QUANTITY: 172 individually ctnd. btls. at Denver, Colo.

SHIPPED: 2-2-62, from Glendale, Calif., by Lawrie Laboratories.

LABEL IN PART: (Btl. and ctn.) "Verdesol Oral Solution is indicated for Daily Oral Hygiene * * * Active Ingredients: Chlorophyll, Urea, Sodium Borate, Sodium Chloride, Glycerine, and Sodium Ethyl Mercuri Thiosalicylate (Lilly) 1:5000 * * * Lawrie Laboratories, Glendale, Calif."

ACCOMPANYING LABELING: Leaflets entitled "Verdesol Oral Solution."

LIBELED: 3-28-62, Dist. Colo.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was adequate and effective as a treatment for tender, painful areas, canker sores, denture soreness, tender gums, oral conditions and infections, cold sores, fever blisters, sore throat, and acute nasal congestion; that it would allay throat inflammation; maintain and stimulate normal tissue tone; relieve soreness; inhibit denture breath; that it was effective against bacteria associated with tooth decay; and that it was nontoxic and nonirritating.

DISPOSITION: 5-11-62. Default—destruction.

7451. Apinol. (F.D.C. No. 45708. S. No. 58-300 R.)

QUANTITY: 131 2-oz. btls. at Spartanburg, S.C.

SHIPPED: 7-19-60 and 12-30-60, from Greensboro, N.C., by The Apinol Corp.

LABEL IN PART: (Btl.) "Apinol The Pine Antiseptic Distributed by The Apinol Corp. Greensboro, N.C. * * * Active Ingredient: Pine Oil."

LIBELED: 4-17-61, W. Dist. S.C.

CHARGE: 502(a)—when shipped, the bottle and carton labels of the article contained false and misleading representations that the article was adequate and effective as a healing treatment for minor injuries, cuts, bruises, superficial burns, abrasions, sunburns, ringworm, athlete's foot, toothache, and sore throat.

DISPOSITION: On 5-19-61, T. R. Whitson, president of The Apinol Corp., Greensboro, N.C., filed an answer to the libel and also filed a motion to transfer the action to the Middle District of North Carolina. On 8-13-62, claimant withdrew his motion to transfer and, on 10-8-62, withdrew the claim and agreed to the forfeiture of the article. On 11-7-62, an order of condemnation, forfeiture and destruction was entered.

7452. Gelatin capsules. (F.D.C. No. 47695. S. No. 68-318 T.)

QUANTITY: 432 100-capsule boxes and 660 50-capsule boxes, at Chicago, Ill.

SHIPPED: Prior to 6-13-62, from Oakland, Calif., by Ray Drug Co., Inc.

LABEL IN PART: (Box) "Plus Vitamin A and Calcium Nail Aid Gelatin Capsules" and (insert) "100 [or "50"] 12 Grain Capsules Nail Aid Gelatin Capsules Enriched with Vitamin A and Calcium * * * Each capsule contains U.S.P. high protein Gelatin with natural amino acids, Calcium Gluconate and Vitamin A 1667 U.S.P. Units * * * Ray Drug Co., Inc., Distributor, Oakland, Calif."

LIBELED: 6-28-62, N. Dist. Ill.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was adequate and effective to grow stronger and healthier fingernails.

DISPOSITION: 8-2-62. Default—destruction.

7453. Akni-Tabs tablets. (F.D.C. No. 48072. S. No. 70-637 T.)

QUANTITY: 634 60-tablet btls. and 499 120-tablet btls. at Minneapolis, Minn., in possession of Atkinson Drug.

SHIPPED: 7-9-62, from Verona, Pa.

LABEL IN PART: (Btl.) "Akni-Tabs Special Formula Vitamins A Special Multi-Vitamin Formula More Complete Dietary Protection Contents * * * Distributed by Atkinson Laboratories * * * Excelsior, Minnesota."

ACCOMPANYING LABELING: Leaflets entitled "The Relation of Diet and Health to Pimples and Acne and the correctional value of Akni-Tabs Special Formula Vitamins."

RESULTS OF INVESTIGATION: The dealer had prepared the accompanying labeling for the purpose of promoting sales of the article, and distributed the accompanying labeling to prospective customers and mailed it with each order of the product.

LIBELED: 8-28-62, Dist. Minn.

CHARGE: 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the treatment and prevention of pimples, acne, constipation, endocrine imbalance, allergies, emotional disorders, and poor health.

DISPOSITION: 9-5-62. Consent—claimed by Lawrence M. B. Atkinson, Excelsior, Minn. The article was relabeled and the leaflets destroyed.

7454. Beautyslim tablets. (F.D.C. No. 47430. S. No. 26-555 T.)

QUANTITY: 46 80-tablet btls., 35 160-tablet btls., and 23 320-tablet btls., at Toledo, Ohio.

SHIPPED: 1-23-62, from Detroit, Mich., by Beautyslim Associates.

LABEL IN PART: (Btl.) "Beautyslim Tabs Reducing Plan New! Improved * * * Organic Reducing Aid—Pleasant and easy to take special combination of proteins (amino acids), vitamins, minerals, and essential lipoids. * * * Manufactured Exclusively for Beautyslim Associates Detroit, Michigan" and (label on top of btl.) "Toasted Walnut Flavour Delightful to Munch."

ACCOMPANYING LABELING: Leaflet reading in part "Dear Beautyslim Consumer: * * * Medically Speaking * * * Beautyslim Menu."

LIBELED: 4-5-62, N. Dist. Ohio.

CHARGE: 502(a)—when shipped, the name of the article and the following representation in its labeling were false and misleading, namely, that the article was adequate and effective to reduce, control weight, promote beauty, a youthful life, longevity, proper liver function, normalize the body, control the appetite, promote strength and health of youngsters, and that the article was of significant value for special dietary supplementation and therapeutic use by reason of its protein content.

DISPOSITION: On 4-23-62, Vickie Zee, t/a Beautyslim Associates, filed a claim to the article. On 5-12-62, the claimant filed an answer denying that the article was misbranded. On 10-19-62, a consent decree of condemnation and destruction was filed.

7455. Oxygen inhalant. (F.D.C. No. 48270. S. No. 42-009 V.)

QUANTITY: 21 cases, each containing 7 individually ctn'd. cylinders, at Atlantic City, N.J.

SHIPPED: 5-3-62, from Norristown, Pa., by Lif-O-Gen, Inc.

LABEL IN PART: (Cylinder and ctn.) "Emergency Oxygen Lif-O-Gen Oxygen Inhalant Pure Oxygen (U.S.P.) For First Aid and Emergency Use in cases where Oxygen is required or indicated. * * * Distributed by Lif-O-Gen, Inc., 247 Kings Highway East, Haddonfield, N.J. Directions * * * Content Approximately 7 gal. Pure U.S.P. Oxygen * * * Caution"; (envelope in ctn.) "Lif-O-Gen Disposable Mask"; (counter display ctn. in each case) "Lif-O-Gen * * * Be Prepared for Emergencies."

ACCOMPANYING LABELING: Leaflet in carton and cases "For emergencies or whenever needed Lif-O-Gen * * *" and brochures "Now available for your patients Lif-O-Gen * * *."

RESULTS OF INVESTIGATION: Examination showed the article to be a portable, aluminum cylinder, approximately three inches in diameter and 11 inches high, accompanied by a face mask.

LIBELED: 11-8-62, Dist. N.J.

CHARGE: 502(a)—when shipped, the labeling contained statements which represented and suggested to the laity that the article was adequate and effective as a treatment for overcoming shortness of breath, in heart conditions, acute bronchial congestion, asthma, croup, all conditions in which cyanosis is evident, asphyxia, smoke inhalation, accidental strangulation, dyspnea or tachycardia, cardiac arrhythmia, fast heart rate, lowering pulmonary heart pressure, and prevention of pulmonary edema, which statements were false and misleading since the article was not adequate and effective for such purposes and/or since such conditions were not amenable to self-diagnosis and treatment by the laity.

DISPOSITION: 1-18-63. Consent—claimed by Lif-O-Gen, Inc., and relabeled.

7456. Tubin Ion-O-Matic Air Improver device. (D.D.C. No. 48078. S. No. 47-292 T.)

QUANTITY: 10 devices at Newport, Ark.

SHIPPED: 7-25-62, from Los Angeles, Calif., by Tubin Ion-O-Matic, Inc.

LABEL IN PART: (Ctn.) "Air Ionizer Tubin Ion-O-Matic, Inc., Los Angeles 6, Calif."

ACCOMPANYING LABELING: Leaflets entitled "Instructions * * * Tubin Ion-O-Matic Air Improver," "Science Pulls Health Magic Out of Air," "Ions Can Do Strange Things to You," "Tubin Ion-O-Matic Air Improver," and "Daily Racing Form * * * Ionizer Vitalizes 'Sleepy' Doc Jockey."

RESULTS OF INVESTIGATION: Investigation indicated the device to be a small open-ended box containing a high-voltage power supply, corona discharge ionizer, and a fan.

LIBELED: 9-12-62, E. Dist. Ark.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for relieving or overcoming hay fever, asthma, and other respiratory ailments; reducing high blood pressure caused by hypertension or nervous tension; exhilarating the mentally depressed; preventing mucous-block in throat and nasal passages; reducing pain associated with various ailments; aiding and healing wounds; and that negative ions had a beneficial effect on vision, emotional stability, and sexual activity.

DISPOSITION: 1-4-63. Default—4 devices delivered to the Food and Drug Administration and the remainder destroyed.

7457. Sandals. (F.D.C. No. 48079. S. No. 64-942 T.)

QUANTITY: 4,607 pairs in various sizes, colors, and models at Long Beach, Calif., in possession of Berkemann California Co.

SHIPPED: Between 7-1-60 and 6-1-62, from Hamburg, West Germany.

LABEL IN PART: (Ctn.) "Berkemann Fuss-gymnastic Sandale Nach Prof. Thomsen (various sizes, colors and model numbers) Made in West Germany."

ACCOMPANYING LABELING: Leaflets entitled "Happy Feet," "Better Patient Care," "Triple Guarantee," "Here are some startling facts," "Happiness Afoot," "30 Day No Risk Trial," "Price List," "Sales Program," "Order Form," "Berkemann Foot Exercising Sandals," "Argumente," and "Arzte-Urteile Uber Die."

RESULTS OF INVESTIGATION: The accompanying labeling was in part shipped from Hamburg, West Germany, and in part, printed locally by Berkemann California Co. Examination showed the article to be a shoe-sandal of sculptured wood sole which had a rubber bottom and was fitted with wide leather straps.

LIBELED: 9-5-62, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was adequate and effective as a treatment for giving better foot health; regaining foot strength and suppleness; eliminating soreness of the feet; strengthening weak arches; eliminating splayfoot and pain in the upper leg and back regions; relieving and preventing foot troubles and varicose veins; improving circulation; and stimulating flow of blood to the heart.

DISPOSITION: 12-4-62. Consent—claimed by Berkemann California Co. and relabeled.

7458. Scalp stimulator and Beautylift devices. (F.D.C. No. 47448. S. No. 53-076 T.)

QUANTITY: 58 *Beautylift* devices and 63 *scalp stimulator* devices, at Seattle, Wash.

SHIPPED: 2-20-62, from Fullerton, Calif., by Gabrielle Products.

LABEL IN PART: (Devices) "Gabrielle Prods. Fullerton, Calif. [the Beauty-lift devices being additionally labeled "Beautylift"]."

ACCOMPANYING LABELING: Chart entitled "Only By Exercise Can You Tone And Firm Muscles"; manual entitled "Beauty Lift Electronic Facial Exercise"; leaflet entitled "Electro-Therapy for Thinning Hair—First Sign of Baldness"; and letters reading in part "To our favorite customer: Congratulations in taking your first step to a younger look" and "To our Preferred Customer: Congratulations! By the purchase of the electronic sinusoidal stimulator you have taken the first step to a more healthy, vibrant head of hair."

RESULTS OF INVESTIGATION: Investigation indicated that the articles were identical and that they were similar in size and shape to an electric shaver. They consisted of a plastic housing containing electrical circuiting and were equipped with an electrical cord for connection to ordinary house current. Attachments consisted of two plastic sponges intended to be affixed to either side of the device by which electrical impulses were conducted to the person of the user.

LIBELED: 4-16-62, W. Dist. Wash.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the *scalp stimulator device* was an adequate and effective treatment for the prevention of baldness, improvement of muscle tone, firming of skin tissue, and prevention of falling hair by causing the hair to absorb sebum and thereby preventing the hair shaft from breaking off beneath the surface of the skin; and that the *Beautylift device* was an adequate and effective treatment for the prevention of the changes of facial contour associated with the aging process, for the firming of facial muscles, and prevention of stretching and sagging of the skin; and that the use of the *Beautylift device* would firm and tone deep-lying muscles and stimulate circulation.

DISPOSITION: 10-30-62. Consent—claimed by Gabrielle Contouring Equipment Co., Fullerton, Calif., and brought into compliance with the law.

7459. Magnetic bracelets. (F.D.C. No. 48339. S. No. 39-906 V.)

QUANTITY: 228 gold-colored bracelets at San Juan, P.R., in possession of the dealer, Bonido Rivera, Rimar, Inc.

SHIPPED: 8-28-62, from Panama.

ACCOMPANYING LABELING: Leaflets reading in part "Extracted from the Associated Press of 'The Star of Panama' newspaper dated August 6, 1962."

RESULTS OF INVESTIGATION: Examination showed that the article was a metal expansion-type bracelet consisting of slightly magnetic links.

The leaflets were printed in Puerto Rico on order of the dealer.

LIBELED: 10-25-62, Dist. P.R.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was adequate and effective as a treatment for providing longer and more active life and relieving arthritis; and that the article was beneficial to health because it was capable of inhibiting bacterial growth.

DISPOSITION: 2-12-63. Default—destruction.

DRUG FOR VETERINARY USE*

7460. Kow-Kare. (F.D.C. No. 47603. S. No. 8-298 T.)

QUANTITY: 47 cases, 12 2¾-lb. pkgs. each, at Broad Brook, Conn.

SHIPPED: 3-15-62, from Lyndonville, Vt., by Dairy Association Co., Inc.

LABEL IN PART: (Pkg.) "Kow-Kare * * * 1 ounce furnishes: 8000 U.S.P. Units Vitamin A 10,000 U.S.P. Units Vitamin D₂ 87 I.U. Vitamin E."

ACCOMPANYING LABELING: Leaflets entitled "Good Profits."

LIBELED: 5-18-62, Dist. Conn.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective as a treatment for assuring proper daily nutrient balance in dairy cattle to give higher milk production, better breeding, longer milking life, and improved cow health.

DISPOSITION: 12-8-62. Default—the article was delivered to a Federal institution and the leaflets were destroyed.

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¹ (7451, 7454) Seizure contested.

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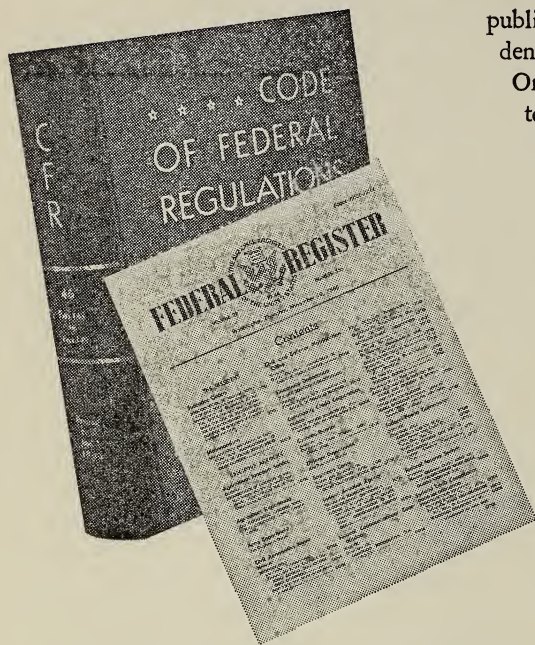
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¹ (7451, 7454) Seizure contested.

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732 Vol

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

7461-7500

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b)(1) and thereby resulted in the dispensed drugs being misbranded while held for sale. Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., May 13, 1964.

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727-449-64

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CURRENT SERIAL RECORDS

VIOLATIVE SALES OF PRESCRIPTION DRUGS

7461. (F.D.C. No. 48148. S. Nos. 6-668 T, 8-492 T, 8-841 T, 8-844 T, 8-846 T, 8-850 T, 8-852 T.)

INFORMATION FILED: 10-30-62, Dist. Mass., against Union Drug Co. (a corporation), Malden, Mass., Themistocles P. D'Elia (president), and Edward R. Mulcahy (employee).

CHARGE: Between 1-23-62 and 3-30-62, *amphetamine sulfate tablets* were dispensed 7 times without a prescription.

PLEA: Nolo contendere by Mulcahy to 2 counts and by the corporation and D'Elia to all counts.

DISPOSITION: On 4-9-63, the corporation was fined \$1,000; D'Elia was fined \$250 and placed on probation for 2 years. On 9-9-63, Mulcahy was placed on probation for 6 months.

7462. (F.D.C. No. 48529. S. Nos. 37-581/3 T, 59-869 T, 59-871/2 T.)

INFORMATION FILED: 5-10-63, M. Dist. Ala., against Bonnie B. Bailey, t/a Crescent Truck Stop, Prattville, Ala.

CHARGE: Between 8-18-62 and 10-10-62, *amphetamine sulfate tablets* were dispensed 5 times and *pentobarbital sodium capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6-6-63. Imprisonment for 2 years.

7463. (F.D.C. No. 48532. S. Nos. 698/9 T.)

INFORMATION FILED: 3-28-63, N. Dist. Ga., against William Conrad Moon, Decatur, Ga.

CHARGE: Between 8-10-62 and 8-11-62, *amphetamine sulfate tablets* and *tablets containing a mixture of amphetamine sulfate and dextro-amphetamine sulfate* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 7-3-63. Sentence of probation for 2 years.

7464. (F.D.C. No. 48878. S. Nos. 77-407 T, 77-409/10 T, 77-415/17 T.)

INFORMATION FILED: 6-24-63, N. Dist. Ga., against Ruby Scott, t/a Scott's Service Station, Atlanta, Ga.

CHARGE: Between 6-2-62 and 6-30-62, *amphetamine sulfate tablets* were dispensed 4 times, and *dextro-amphetamine sulfate tablets* and *tablets containing a mixture of amphetamine sulfate and dextro-amphetamine sulfate* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 7-18-63. \$200 fine, and probation for 2 years.

7465. (F.D.C. No. 45215. S. Nos. 29-193 P, 29-198 P, 74-021 P, 74-032 P, 74-037/8 P.)

INFORMATION FILED: 2-13-61, N. Dist. Ala., against George C. McGinnis, t/a Clearview Truck Stop, Springville, Ala., and William C. Noulis, Johnny Reno, and Mina Stoffregen (employees).

CHARGE: Between 8-13-59 and 9-11-59, *dextro-amphetamine sulfate tablets*, and *tablets containing a mixture of amphetamine sulfate and dextro-ampheta-*

mine sulfate were each dispensed twice and *amphetamine sulfate tablets* were dispensed once, without a prescription.

PLEA: Guilty by McGinnis to 5 counts; by Reno and Noulín to 2 counts each; and by Stoffregen to 1 count.

DISPOSITION: 11-7-61. Reno—probation for 3 years. 12-11-61. McGinnis and Stoffregen—\$250 fine each. 1-3-62. Noulín—\$250 fine.

7466. (F.D.C. No. 48931. S. Nos. 15-361 V, 15-366 V.)

INFORMATION FILED: 8-15-63, W. Dist. Ky., against Charles Lester Key, t/a Dance Truck Stop, Smiths Grove, Ky.

CHARGE: Between 9-14-62 and 11-1-62, *dextro-amphetamine sulfate capsules* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 11-11-63. \$500 fine.

7467. (F.D.C. No. 49143. S. Nos. 14-286 T, 14-297 T.)

INFORMATION FILED: 9-24-63, N. Dist. Ill., against Apothecaries, Inc., t/a Boehning's Apothecary, Chicago, Ill., and John F. Boehning (president and assistant pharmacist).

CHARGE: Between 2-2-62 and 6-6-62, *dextro-amphetamine sulfate capsules* and *Equanil tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11-13-63. Corporation and individual fined \$200 each, plus costs.

7468. (F.D.C. No. 47110. S. Nos. 83-983/5 R.)

INFORMATION FILED: 9-13-62, Dist. N.J., against Palace Drug Stores, Inc., Jersey City, N.J., Martin Kurlan (treasurer and pharmacist), and Jack Mazer (secretary and pharmacist).

CHARGE: On 6-2-61, *dextro-amphetamine sulfate tablets*, *phenobarbital tablets* and *Tuinal capsules* were each dispensed once without a prescription.

PLEA: Nolo contendere by the individuals to the counts involving *dextro-amphetamine sulfate tablets* and *phenobarbital tablets*; and guilty by the corporation to all 3 counts.

DISPOSITION: 11-15-63. Corporation—\$1,500 fine; Mazer—\$1,000 fine; Kurlan—\$500 fine.

7469. (F.D.C. No. 47112. S. Nos. 60-901/08 R.)

INFORMATION FILED: 7-30-62, S. Dist. Miss., against Warren W. Brown, t/a Court House Drug Store, Meridian, Miss.

CHARGE: Between 2-28-61 and 4-6-61, *Dexedrine Sulfate tablets* were dispensed 4 times, *Diuril tablets* were dispensed twice, and *Meticorten tablets* and *secobarbital sodium capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 9-11-62. \$150 fine.

7470. (F.D.C. No. 48191. S. Nos. 38-261/7 T.)

INFORMATION FILED: 8-22-63, S. Dist. Ala., against Edgar Herman Melton (pharmacist), Brewton, Ala.

CHARGE: Between 4-17-62 and 4-25-62, *Dexedrine Sulfate tablets* were dispensed 3 times, *Butisol Sodium tablets* were dispensed twice, *Meticorten tablets*, and *Dexedrine Spansule capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 9-27-63. \$500 fine.

7471. (F.D.C. No. 48900. S. Nos. 31-965 T, 31-968/9 T.)

INFORMATION FILED: 7-23-63, Dist. Nev., against **Fifth Avenue Drug (a partnership)**, Las Vegas, Nev., and **Charles K. Hoffman** (partner and pharmacist).

CHARGE: Between 4-12-62 and 5-3-62, *Dexedrine Sulfate tablets* were dispensed twice and *Equanil tablets* were dispensed once upon requests for prescription refills without obtaining authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 10-18-63. Partnership—\$300 fine; Hoffman—1 year in prison suspended, \$300 fine, and probation for 1 year.

7472. (F.D.C. No. 48519. S. No. 1-997 T.)

INFORMATION FILED: 2-12-63, M. Dist. Ga., against **Marcus R. Johnson**, t/a 41 Inn, Barnesville, Ga.

CHARGE: On 3-21-62, *capsules containing a mixture of amobarbital and dextro-amphetamine sulfate* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4-19-63. Probation for 3 years.

7473. (F.D.C. No. 47882. S. Nos. 69-604/9 T, 69-801 T.)

INFORMATION FILED: 2-20-63, Dist. Md., against **Ralph F. Young, M.D., Williamsport, Md.**

CHARGE: Between 4-24-62 and 5-16-62, *tablets containing a combination of amphetamine sulfate, thyroid and aloin*, *tablets containing a combination of amphetamine sulfate and thyroid*, and *tablets containing a combination of amphetamine sulfate, phenobarbital and thyroid* were each dispensed 5 times, and *tablets containing a combination of dextro-amphetamine sulfate and amobarbital* were dispensed 4 times without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 12-4-63. \$5,000 fine, plus costs, and probation for 2 years.

7474. (F.D.C. No. 48567. S. Nos. 64-122 T, 64-125 T, 64-141 T, 64-157 T, 64-177 T, 64-356 T, 64-361 T, 64-529 T, 64-532 T, 64-536 T, 64-547 T.)

INFORMATION FILED: 6-4-63, E. Dist. S.C., against **John K. Allen** (pharmacist), **Johnsonville, S.C.**

CHARGE: Between 5-24-62 and 9-13-62, *Benzedrine tablets* were dispensed 5 times, *dextro-amphetamine sulfate tablets* were dispensed 3 times, *Carbrital Kapseals* were dispensed twice, and *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 9-30-63. \$250 fine or 6 months in prison.

7475. (F.D.C. No. 47074. S. Nos. 388 R, 401/4 R.)

INDICTMENT RETURNED: 8-17-62, S. Dist. Ind., against Theodore A. Wheaton, t/a Wheaton's Pharmacy, Mt. Vernon, Ind., and Paul B. Ringham (pharmacist).

CHARGE: Between 4-5-61 and 7-13-61, *Butazolidin tablets* were dispensed 3 times and *Miltown tablets* and *Equanil tablets* were each dispensed once without a prescription.

PLEA: Nolo contendere by Wheaton to 5 counts; by Ringham to 4 counts.

DISPOSITION: 9-4-62. Wheaton—\$450 fine. 9-11-62. Ringham—\$300 fine.

7476. (F.D.C. No. 47075. S. Nos. 67-044/8 R, 67-054/5 R, 67-057/9 R.)

INFORMATION FILED: 6-25-62, S. Dist. Tex., against Dugan Drug Stores, Inc., Houston, Tex., and James S. Dugan (president), and Gerald Millslagle, Daniel E. Morse, Jose M. Carrillo, and Clifford A. Rogers (pharmacists).

CHARGE: Between 3-6-61 and 3-14-61, *Declomycin hydrochloride capsules* were dispensed 3 times and *triamcinolone tablets*, *meprobamate tablets*, *methylprednisolone tablets*, and *chlorpromazine hydrochloride tablets* were each dispensed twice upon request for prescription refills without authorization from a prescriber.

PLEA: Not guilty by Dugan Drug Stores, Inc., and James S. Dugan to all counts, by Millslagle and Morse 2 counts, and by Carrillo to 1 count; guilty by Rogers to 2 counts.

DISPOSITION: On 3-22-63, after a trial by jury, a verdict of guilty against Dugan Drug Stores, Inc., was rendered and a verdict of not guilty against Dugan, Millslagle, Morse, and Carrillo was returned. On 3-29-63, corporation was fined \$2,500. On 4-5-63, Rogers was fined \$200 and placed on probation for 3 years; a sentence of 3 months' imprisonment was suspended.

7477. (F.D.C. No. 48199. S. Nos. 57-210/17 T.)

INFORMATION FILED: 3-18-63, W. Dist. Okla., against J. Reuel Campbell, t/a Britton Drug Store, Oklahoma City, Okla.

CHARGE: Between 3-22-62 and 4-3-62, *meprobamate tablets* were dispensed twice without a prescription, and *capsules of amobarbital sodium and secobarbital sodium*, *Dexedrine Spansule capsules* and *benzphetamine hydrochloride tablets* were each dispensed twice upon request for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 4-8-63. \$800 fine.

7478. (F.D.C. No. 48889. S. Nos. 64-461 T, 2-449 V.)

INFORMATION FILED: 6-28-63, S. Dist. Fla., against Don's Drugs, Inc., South Miami, Fla., and Donald F. Pulley (president).

CHARGE: Between 7-21-62 and 9-29-62, *Miltown tablets* and *penicillin G potassium tablets* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 7-26-63. Corporation—\$1,000 fine; Pulley—\$500 fine, and probation for 3 years.

7479. (F.D.C. No. 48884. S. Nos. 696/7 T, 700 T, 3 V.)

INFORMATION FILED: 9-30-63, N. Dist. Ga., against William Thomas Greeson, Auburn, Ga.

CHARGE: Between 7-19-62 and 10-11-62, *pentobarbital sodium capsules* were dispensed 3 times and *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 10-24-63. \$600 fine and probation for 2 years.

7480. (F.D.C. No. 47306. S. Nos. 47-671/80 R.)

INFORMATION FILED: 4-23-63, E. Dist. Mich., against Chester W. Bower, t/a Bower's Drug Store, Detroit, Mich., and Timothy Miller, Jr. (pharmacist).

CHARGE: Between 2-28-61 and 5-18-61, *Pen-Vee-Oral tablets* were dispensed 3 times, *penicillin G potassium tablets* and *dextro-amphetamine sulfate tablets* were each dispensed twice without a prescription.

PLEA: Guilty by Bower to 7 counts; by Miller to 4 counts.

DISPOSITION: 8-8-63. Bower—\$500 fine and probation for 2 years; Miller—\$200 fine and probation for 2 years.

7481. (F.D.C. No. 46657. S. Nos. 66-964/6 R.)

INFORMATION FILED: 5-29-62, S. Dist. Tex., against Ed Charles Froebel, t/a Stephen's Pharmacy, Houston, Tex.

CHARGE: Between 3-3-61 and 3-7-61, *reserpine tablets*, *Seconal Sodium capsules* and *dextro-amphetamine sulfate tablets* were each dispensed once upon request for a prescription refill without obtaining authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 7-20-62. \$1,000 fine.

7482. (F.D.C. No. 47890. S. Nos. 23-388 T, 23-392 T.)

INFORMATION FILED: 9-13-62, Dist. Colo., against Cooper Drug, Inc., Denver, Colo., and Everett Martinez (president).

CHARGE: Between 5-24-62 and 5-25-62, *Seconal Sodium capsules* and *amphetamine sulfate tablets* were each dispensed once with a prescription.

PLEA: Guilty.

DISPOSITION: 7-8-63. Corporation—\$1,000 fine; Martinez—\$2,000 fine suspended, and probation for 3½ years.

7483. (F.D.C. No. 48913. S. Nos. 64-346 T, 64-362 T, 88-360 T, 88-366 T, 88-369 T, 88-374 T, 167 V, 172 V, 176 V, 426 V.)

INFORMATION FILED: 8-26-63, E. Dist. S.C., against Duncan S. Farrow, t/a Colonial Drug Store, Florence, S.C., Ward S. Woodard (employee), and Laurie E. Suggs (pharmacist).

CHARGE: Between 6-19-62 and 10-31-62, *Thorazine tablets* were dispensed 7 times and *Librium Hydrochloride capsules* were dispensed 3 times upon requests for prescription refills without obtaining authorization by the prescriber.

PLEA: Guilty by Farrow to 5 counts; by Suggs to 3 counts; and by Woodard to 2 counts.

DISPOSITION: 9-30-63. Farrow—\$500 fine or 6 months in prison; Woodard and Suggs each—\$300 fine or 6 months in prison.

7484. (F.D.C. No. 48179. S. Nos. 6-574 T, 6-577 T, 8-372 T, 8-374 T, 8-630 T, 8-634 T, 8-639 T, 8-922/7 T.)

INFORMATION FILED: 1-7-63, Dist. Mass., against **South Peabody Pharmacy, Inc., Peabody, Mass., Louise B. Evitts (president), and Eugene Boudreau and Arnold Cort (pharmacists).**

CHARGE: Between 3-28-62 and 5-14-62, *Tuinal capsules* were dispensed 6 times and *Dexedrine Sulfate tablets* were dispensed 5 times upon requests for prescription refills without authorization by the prescribers, *Tuinal capsules* were also dispensed twice without a prescription.

PLEA: Not guilty by Arnold Cort to counts 3, 6, 9, 10, 11, and 13 of the information, guilty by the corporation and Louise Evitts to all 13 counts of the information, and guilty by Eugene Boudreau to 1 count.

DISPOSITION: On 3-15-63, the corporation was fined \$1,000; Louise Evitts was given a suspended sentence of 1 year in jail, fined \$1,500 and placed on probation for 2 years; and Eugene Boudreau was fined \$100 and placed on probation for 2 years.

The case against Arnold Cort came to trial before the court and jury on 3-19-63. The trial was concluded on 3-26-63, with a directed verdict of acquittal.

7485. (F.D.C. No. 48523. S. Nos. 59-882/5 T.)

INFORMATION FILED: 2-14-63, N. Dist. Ala., against **Chancellor Elrod (a truck stop employee), Cullman, Ala.**

CHARGE: Between 8-17-62 and 8-20-62, *desoxyephedrine hydrochloride tablets* were dispensed 3 times and *tablets containing a mixture of dextro-amphetamine sulfate and amphetamine sulfate* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 3-4-63. Sentence of 1 year and 1 day in jail suspended, and probation for 1 year.

7486. (F.D.C. No. 48522. S. Nos. 59-874/5 T.)

INFORMATION FILED: 2-13-63, M. Dist. Ala., against **Pete Brown (a truck stop employee), Georgiana, Ala.**

CHARGE: On 8-18-62, *desoxyephedrine hydrochloride tablets* and *tablets containing a mixture of dextro-amphetamine sulfate and amphetamine sulfate* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4-19-63. Sentence of 1 year in jail, of which 6 months was to be served and the remainder suspended, and probation for 3 years.

7487. (F.D.C. No. 48927. S. Nos. 72-641 T, 72-643 T, 72-648 T, 15-415 V.)

INFORMATION FILED: 7-19-63, S. Dist. Ind., against **Melvin Thomas Holder, t/a Tree Truck Stop, Palmyra, Ind.**

CHARGE: Between 6-15-62 and 10-19-62, *desoxyephedrine hydrochloride tablets* and *amphetamine sulfate tablets* were each dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 8-9-63. \$1,000 fine, plus costs.

7488. (F.D.C. No. 49133. S. Nos. 15-375/6 V.)

INFORMATION FILED: 9-13-63, N. Dist. Ind., against **Joseph T. Faulkner, Jr.** (drug manufacturer's salesman), **Ft. Wayne, Ind.**

CHARGE: On 11-3-62, *desoxyephedrine hydrochloride tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11-14-63. Sentence of 1 year in prison suspended, and probation for 6 months.

7489. (F.D.C. No. 49132. S. Nos. 72-645 T, 72-649 T, 15-371 V, 15-374 V.)

INFORMATION FILED: 9-18-63, S. Dist. Ind., against **Richard S. Faulkner** (drug manufacturer's salesman), **Ft. Wayne, Ind.**

CHARGE: Between 7-13-62 and 10-24-62, *desoxyephedrine hydrochloride tablets* were dispensed 3 times and *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10-4-63. \$1,400 fine, plus costs.

7490. (F.D.C. No. 48874. S. Nos. 45-922 V, 45-928 V.)

INFORMATION FILED: 7-1-63, E. Dist. Ill., against **Ambrose D. Schneider, M.D., Donovan, Ill.**

CHARGE: Between 12-14-62 and 1-7-63, *desoxyephedrine hydrochloride tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 12-20-63. \$1,500 fine and probation for 2 years.

7491. (F.D.C. No. 46374. S. Nos. 75-245/9 R.)

INFORMATION FILED: 10-4-61, N. Dist. Ga., against **James C. Holbrook** (truck stop employee), **Toccoa, Ga.**

CHARGE: Between 4-17-61 and 4-26-61, *tablets containing a mixture of amphetamine sulfate and dextro-amphetamine sulfate* were dispensed 5 times without a prescription.

PLEA: Guilty.

DISPOSITION: 4-18-62. Imprisonment for 6 months.

7492. (F.D.C. No. 46366. S. Nos. 1-546 R, 1-556 R, 1-558 R, 3-147 R, 75-243 R.)

INFORMATION FILED: 10-4-61, N. Dist. Ga., against **Lonnie P. Holbrook**, **Toccoa, Ga.**

CHARGE: Between 3-29-61 and 4-12-61, *tablets containing a mixture of amphetamine sulfate and dextro-amphetamine sulfate* were dispensed 5 times without a prescription.

PLEA: Guilty.

DISPOSITION: 4-18-62. \$125 fine and probation for 2 years.

7493. (F.D.C. No. 48533. S. Nos. 540 T, 654 T, 2-000 T, 76-903 T, 76-921 T, 77-402 T.)

INFORMATION FILED: 4-12-63, N. Dist. Ga., against **Clifford M. Ferguson** (employee of a truck stop), **Adairsville, Ga.**

CHARGE: Between 4-10-62 and 5-21-62, *tablets containing a mixture of amphetamine sulfate and dextro-amphetamine sulfate* were dispensed 6 times without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 6-3-63. Sentence of probation for 2 years.

7494. (F.D.C. No. 48561. S. Nos. 1-967/9 T.)

INFORMATION FILED: 5-31-63, N. Dist. Ga., against Alger A. Morgan (employee of a truck stop), Atlanta, Ga.

CHARGE: Between 2-2-62 and 2-9-62, *tablets containing a mixture of amphetamine sulfate and dextro-amphetamine sulfate* were dispensed twice, and *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 7-17-63. Sentence of probation for 2 years.

7495. (2 criminal cases) (F.D.C. Nos. 47062, 47327. S. Nos. 22-611 R, 22-828 R, 24-136 R, 85-787 R.)

INFORMATION FILED: 4-18-62, Dist. Kans., against Larry Dean Mead, t/a "317 Club," Kansas City, Kans.; and 4-20-62, W. Dist. Mo., against Larry Dean Mead.

CHARGE: Between 3-14-61 and 5-16-61, *amphetamine hydrochloride tablets* were dispensed twice and *amphetamine sulfate tablets* were dispensed once without a prescription, at Kansas City, Kans.

On 6-26-61, *amphetamine sulfate tablets* were dispensed once without a prescription, at Kansas City, Mo.

PLEA: Guilty.

DISPOSITION: On 5-25-62, the Kansas City, Mo., case was transferred to the District of Kansas. On 7-2-62, the defendant was fined \$500, plus costs, and placed on probation for 2 years in the Kansas City, Kans., case. The defendant was also given a sentence of 2 years' probation in the Kansas City, Mo., case to run concurrently with the sentence in the former case.

7496. (F.D.C. No. 47123. S. Nos. 47-101/9 R.)

INFORMATION FILED: 6-28-63, E. Dist. Mich., against Philip J. Forman, t/a Phillip's Pharmacy, Detroit, Mich.

CHARGE: Between 1-19-61 and 3-22-61, *penicillin G potassium tablets* were dispensed 5 times, *sulfathiazole tablets* were dispensed 3 times, and *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 8-27-63. \$1,000 fine and probation for 2 years.

7497. (F.D.C. No. 45982. S. Nos. 46-881/2 R, 46-884/5 R, 46-888 R, 46-890 R.)

INFORMATION FILED: 9-20-62, E. Dist. Mich., against Willie E. Flounory and Julius C. Scott (pharmacists), Inkster, Mich.

CHARGE: Between 5-5-60 and 6-8-60, *penicillin G potassium tablets* were dispensed 3 times and *Dexedrine Sulfate tablets* were dispensed twice without a prescription.

PLEA: Not guilty by Scott to 1 count involving penicillin; guilty by Flounory to all other counts.

DISPOSITION: On 1-18-63, Flounory was placed on probation for 2 years. On 7-23-63, the case against Scott came on for trial before the court; the court found Scott guilty. On 10-21-63, Scott was placed on probation for 2 years.

7498. (F.D.C. No. 45583. S. Nos. 87-519 P, 1-563 R, 1-566 R, 1-569 R, 1-575/6 R, 1-581 R, 1-589 R, 1-592/3 R, 1-596/7 R.)

INDICTMENT RETURNED: 8-14-61, M. Dist. Ga., against Ronald G. Shawver, Rochelle, Ga.

CHARGE: Between 2-8-60 and 8-12-60, *secobarbital sodium capsules* were dispensed 9 times and *Equanil tablets* were dispensed 3 times without a prescription.

PLEA: Not guilty.

DISPOSITION: The case went to trial on 1-16-62, before the court and jury and was concluded on 1-17-62, when the jury returned a verdict of guilty. On 1-25-62, the defendant was sentenced to 2 years in prison.

The defendant filed a notice of appeal on 1-26-62, and was released on \$5,000 bond. The defendant was specifically directed by the court that he was not to dispense, prescribe, sell, or give away any drugs while the appeal was pending.

On 7-12-62, the Government filed a motion to revoke the defendant's bail which was heard 8-6-62. The court revoked the defendant's bail with the following order:

BOOTLE, *District Judge*: "The defendant was sentenced on January 26, 1962, and on the same day he presented, through his counsel, Mr. Collier, an application to be released on bail pending an appeal, and on the same day he and his counsel, Mr. Collier, signed a notice of appeal and the Court at that time, without looking into the question of whether the appeal was frivolous or taken for delay only, routinely granted bail, stating at the time:

'Well, in accordance with my usual liberal practice, I think I will allow it and I set his bond at \$5,000 and I tell Mr. Shawver that he had better not prescribe or sell or dispense any more drugs in my jurisdiction, unless he is successful in reversing this conviction in the Court of Appeals or the Supreme Court. Now that means from now, while it is on appeal too. It looks like the state court down there has done all it could to keep you from dispensing and prescribing drugs. You have not cooperated. You still insist that you have a right to dispense drugs when the statutes of Georgia and of Congress specifically say you can't do it, and I am going to grant the supersedeas, but I am not giving him any permission, during the appeal to do what is a dangerous thing, and that is for a man who is not properly licensed by state and/or federal authorities to prescribe or dispense or sell or give away drugs. Very well.'

"Now, I fail myself to see any merit in the appeal, but due to the reluctance of any trial Judge to pass upon the correctness of his own decisions (see *Parsell vs. United States* 218 F. 2d 232 at page 236) I hesitate to and refrain from certifying that the appeal is frivolous, or that it is taken for delay only. As I see it there is only one point which was made during the trial of this case which counsel for the defendant now relies upon as grounds of an appeal and that relates to whether or not the authenticity of the samples used by the microbiologist was sufficiently established. I, of course, think that it was, or I would not have overruled counsel's motion to exclude testimony relating to those samples. No motions for directed verdict or for a judgment of acquittal were made, and no exceptions were taken to the charge of the Court, except by counsel for the Government. The appeal should have been perfected on or before March 7, 1962 and it appears that the record was not ordered from the court reporter until March 26, 1962. The defendant has been so dilatory in the prosecution of his appeal that he has had to apply twice to the Court of Appeals for extensions of time within which to perfect his

appeal, each time in response to a motion of the government counsel to docket and dismiss. Certainly no criticism of the Court of Appeals is intended in their granting the two extensions, but criticism of the defendant for his dilatoriness in making it necessary to ask the indulgence of the Court of Appeals on these two occasions is proper. The appeal, or notice of appeal, was filed on January 26, 1962 and here it is August 6, 1962 without the record, as yet, having been filed in the Court of Appeals, and without any designation of the record having been filed and without any statement of points to be relied on having been filed; all this, notwithstanding the fact that the record was received by the defendant on May 7, 1962, a full three months ago, lacking one day.

"Even if we assume that the appeal is not frivolous or that it is not taken for delay, a point which I do not decide, the inquiry does not end there. Certainly it has been used for delay and in accordance with the recent pronouncement of the Supreme Court bail is to be denied in cases in which, from substantial evidence, it seems clear that the right to bail may be abused 'or the community may be threatened by the applicant's release.' *Leigh vs. United States* — U.S. —, 8 L. Ed. 2d. 269 at p. 271. From the record made at defendant's sentencing it appears that he was once licensed as a chiropractor and that a hearing was had and he voluntarily sent that license in about 1954, and that he was tried in the Superior Court on the charge of practicing medicine without a license. My information is that a plea of *nolo contendere* was entered and that he received a fine of \$150.00 and six months probation with a special condition that he not write prescriptions for any patient. The sentencing record shows the entry of that plea and the receipt of that fine and probation sentence. Then, later in 1960, he was convicted in Wilcox County for violation of the Georgia Medical Practices Act, which conviction seems to have been affirmed by the Court of Appeals of Georgia. He intended to apply to the Supreme Court of Georgia for certiorari, but because of sickness failed to do so. As a part of the sentence in that case his license to practice naturopathy was suspended for six months. Then in a later, unrelated case, about another matter, a part of the probation sentence was, in the state court, that he not write or prepare prescriptions not allowable by law. He said at sentencing that he had complied with that and had not written prescriptions, but that he dispenses the medication that in his opinion is within the scope of his practice.

"This Court tried to make it clear to the defendant at the time of sentencing that he was not to prescribe or sell or dispense any drugs as to which he is not properly licensed by state and/or federal authorities to prescribe or dispense or sell or give away. The evidence here today clearly shows that the defendant, since his conviction and sentence in this court, has continued to sell and dispense drugs which can be legally dispensed only upon prescriptions written by licensed physicians. For instance, he dispensed to Joe D. Whittle, phenobarbital, which is such a drug, about July, 1962; he dispensed to Rosie Martin, hormones, which is such a drug; and he dispensed to George McWhorter on May 15, 1962, adrenalin, nitroglycerin, Wyamine sulfate, and oxygen, all of which are such drugs; and he dispensed to Cecil Harrison a shot of penicillin which is such a drug; and on June 11, 1962 he possessed 73 types of drugs, all of which apparently, with the exception of possibly three to six, are legally limited to prescriptions by licensed physicians. Those drugs included phenobarbital, adrenalin, Wyamine sulfate, nitroglycerin and penicillin.

"Every indication, therefore, is that if the defendant remains at large under bail he is going to continue to dispense drugs which he is not, under the law, permitted to dispense. Obviously this practice holds danger for the community and, therefore, in my judgment, in the language of the Supreme Court 'the community may be threatened by the applicant's release.'

"I feel it my duty, therefore, to revoke defendant's bail.

"So ordered, this 6th day of August, 1962."

On 10-30-62, an order was entered in the U.S. Court of Appeals for the Fifth Circuit dismissing the defendant's appeal because the appellant had failed to file and docket the record on appeal.

7499. (F.D.C. No. 47861. S. Nos. 57-320/1 R, 57-326/7 R, 38-183/5 T, 38-187/9 T, 38-192 T, 38-196 T.)

INFORMATION FILED: 1-19-63, N. Dist. Miss., against City Drug Store (a partnership), Hollandale, Miss., Leroy H. Clay (partner), and John K. Minyard (pharmacist).

CHARGE: Between 11-29-60 and 9-26-61, *secobarbital sodium capsules* were dispensed 5 times, *dextro-amphetamine sulfate tablets* were dispensed 3 times, *Equanil tablets* and *prednisone tablets* were each dispensed once, and *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were dispensed twice, without a prescription.

PLEA: Nolo contendere by partnership to all counts of the information, by Clay to 9 counts, and by Minyard to 3 counts.

DISPOSITION: 3-28-63. Partnership fined \$1,200; individuals placed on probation for 2 years.

7500. (F.D.C. No. 48880. S. Nos. 14-528 T, 14-530 T, 14-533 T.)

INFORMATION FILED: 6-25-63, N. Dist. Ill., against Lan-Ter Medical Supply Co. (a corporation), Chicago, Ill., Joseph P. Lanzarotti (president and pharmacist), and Daniel P. Terracciano (secretary-treasurer and pharmacist).

CHARGE: Between 6-27-62 and 7-13-62, *AM Plus capsules*, *dextro-amphetamine sulfate capsules*, and *Seconal Sodium capsules* were each dispensed once without a prescription.

PLEA: Guilty by Terracciano to the count involving *dextro-amphetamine sulfate capsules*, and by the corporation and Lanzarotti to the counts involving *AM Plus capsules* and *Seconal Sodium capsules*.

DISPOSITION: 12-3-63. Corporation—\$1,000 fine; Lanzarotti—\$1,000 fine; Terracciano—\$500 fine.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 7461 TO 7500

PRODUCTS

	N.J. No.		N.J. No.
AM Plus capsules.....	7500	Amphetamine sulfate, phenobarbital, and thyroid, tablets containing a combination of.....	7473
Amobarbital and dextro-amphetamine sulfate, capsules containing a mixture of.....	7472	Amphetamine sulfate and thyroid, tablets containing a combination of.....	7473
Amobarbital sodium and secobarbital sodium capsules.....	7477	Benzedrine tablets.....	7474
Amphetamine hydrochloride tablets.....	7495	Benzphetamine Hydrochloride tablets.....	7477
dextro-, sulfate capsules.....	7466, 7467, 7500	Butazolidin tablets.....	7475
sulfate tablets.....	7464, 7465, 7468, 7474, 7480, 7481, 7489, 7496, 7499	Butisol Sodium tablets.....	7470
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Amphetamine sulfate and dextro-amphetamine sulfate, tablets containing a mixture of.....	7463-7465, 7491-7494	Chlorpromazine hydrochloride tablets.....	¹ 7476
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		Desoxyephedrine hydrochloride tablets.....	7485-7490

¹ (7476, 7484, 7497) Prosecution contested.

	N.J. No.		N.J. No.
Dexedrine Spansule capsules_	7470, 7477	Miltown tablets_	7475, 7478
Dexedrine sulfate tablets_	7469, 7470, 7471, ¹ 7484, ¹ 7497	Penicillin G potassium tablets_	7478, 7480, 7496, ¹ 7497
Dextro-amphetamine sulfate capsules_	7466, 7467, 7500	Pentobarbital sodium capsules_	7462, 7479
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Dextro-amphetamine sulfate and amobarbital, tablets containing a combination of_	7473	Phenobarbital tablets_	7468
Dextro-amphetamine sulfate and amphetamine sulfate, tablets containing a mixture of_	7485, 7486	Prednisone tablets_	7499
Diuril tablets_	7469	Reserpine tablets_	7481
Equanil tablets_	7467, 7471, 7475, ² 7498, 7499	Secobarbital sodium and amobarbital sodium, capsules containing a mixture of_	7499
Librium Hydrochloride capsules_	7483	Secobarbital sodium capsules_	7469, ² 7498, 7499
Meprobamate tablets_	¹ 7476, 7477	Seconal Sodium capsules_	7481, 7482, 7500
Methylprednisolone tablets_	¹ 7476	Sulfathiazole tablets_	7496
Meticorten tablets_	7469, 7470	Thorazine tablets_	7483
		Triamcinolone tablets_	¹ 7476
		Tuinal capsules_	7468, ¹ 7484

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

	N.J. No.		N.J. No.
Allen, J. K.:		Bower's Drug Store. <i>See</i> Bower, C. W.	
Benzedrine tablets, Carbrital Kapseals, amphetamine sulfate tablets, and dextro-amphetamine sulfate tablets_	7474	Britton Drug Store. <i>See</i> Campbell, J. R.	
Apothecaries, Inc.:		Brown, Pete:	
dextro-amphetamine sulfate capsules and Equanil tablets_	7467	desoxyephedrine hydrochloride tablets and tablets containing a mixture of dextro-amphetamine sulfate and amphetamine sulfate_	7486
Bailey, B. B.:		Brown, W. W.:	
amphetamine sulfate tablets and pentobarbital sodium capsules_	7462	Dexedrine Sulfate tablets, Diuril tablets, Meticorten tablets, and secobarbital sodium capsules_	7469
Boehning, J. F.:		Campbell, J. R.:	
dextro-amphetamine sulfate capsules and Equanil tablets_	7467	meprobamate tablets, capsules of amobarbital sodium and secobarbital sodium, Dexedrine Spansule capsules, and Benzphetamine Hydrochloride tablets_	7477
Boehning's Apothecary. <i>See</i> Apothecaries, Inc.			
Boudreau, Eugene:			
Tuinal capsules and Dexedrine Sulfate tablets_	7484		
Bower, C. W.:			
Pen-Vee-Oral tablets, penicillin G potassium tablets, and dextro-amphetamine sulfate tablets_	7480		

¹ (7476, 7484, 7497) Prosecution contested.² (7498) Prosecution contested. Contains order of the court.

	N.J. No.		N.J. No.
Carrillo, J. M.:		Dugan Drug Stores, Inc.:	
Declomycin hydrochloride capsules, triamcinolone tablets, meprobamate tablets, methylprednisolone tablets, and chlorpromazine hydrochloride tablets-----	1 7476	Declomycin hydrochloride capsules, triamcinolone tablets, meprobamate tablets, methylprednisolone tablets, and chlorpromazine hydrochloride tablets-----	1 7476
City Drug Store:		Elrod, Chancellor:	
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Clay, L. H.:		Evitts, L. B.:	
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Clearview Truck Stop. See McGinnis, G. C.		Farrow, D. S.:	
Colonial Drug Store. See Farrow, D. S.		Thorazine tablets and Librium Hydrochloride capsules-----	7483
Cooper Drug, Inc.:		Faulkner, J. T., Jr.:	
Seconal Sodium capsules and amphetamine sulfate tablets--	7482	desoxyephedrine hydrochloride tablets-----	7488
Cort, Arnold:		Faulkner, R. S.:	
Tuinal capsules and Dexedrine Sulfate tablets-----	1 7484	desoxyephedrine hydrochloride tablets and dextro-amphetamine sulfate tablets-----	7489
Court House Drug Store. See Brown, W. W.		Ferguson, C. M.:	
Crescent Truck Stop. See Bailey, B. B.		tablets containing a mixture of amphetamine sulfate and dextro-amphetamine sulfate--	7493
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amphetamine sulfate tablets--	7461	Flounory, W. E.:	
Don's Drugs, Inc.:		penicillin G potassium tablets and Dexedrine Sulfate tablets-----	7497
Miltown tablets and penicillin G potassium tablets-----	7478	Forman, P. J.:	
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Declomycin hydrochloride capsules, triamcinolone tablets, meprobamate tablets, methylprednisolone tablets, and chlorpromazine hydrochloride tablets-----	1 7476	41 Inn. See Johnson, M. R.	
		Froebel, E. C.:	
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		Greeson, W. T.:	
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¹ (7476, 7484, 7497) Prosecution contested.

	N.J. No.		N.J. No.
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Equanil tablets.....	7471	tablets and amphetamine sul-	
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¹ (7476, 7484, 7497) Prosecution contested.

	N.J. No.		N.J. No.
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¹ (7476, 7484, 7497) Prosecution contested.² (7498) Prosecution contested. Contains order of the court.

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U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

SCIENCE & CULTURE
LIBRARY

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD,
DRUG, AND COSMETIC ACT

JUN 30 1964

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

CURRENT SERIAL RECORDS

7501-7540

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were alleged to be adulterated or misbranded, or otherwise violative of the Act, when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent; and (2) a criminal proceeding which was terminated upon a plea of nolo contendere. The seizure proceedings are civil actions taken against the goods alleged to be in violation, and the criminal proceeding is against the firm and individual charged to be responsible for the violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., June 4, 1964.

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* For omission of, or unsatisfactory, ingredients statements, see Nos. 7506, 7516; failure to bear a label containing an accurate statement of the quantity of the contents, No. 7506; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 7506; cosmetic under the drug provisions of the Act, No. 7538.

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D.D.N.J. NOS. 7501-7540**

Adulteration, Section 501(a) (2), the article had been prepared and packed under insanitary conditions whereby it may have been rendered injurious to health; Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2) in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient including, whether active or not, the quantity or proportion of any derivative or preparation of arsenic contained therein; and Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions where its use might be dangerous to health, in such manner and form, as are necessary for the protection of users.

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application, or an approval of an application, filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

7501. Pentaerythritol tetranitrate capsules. (F.D.C. No. 48772. S. No. 72-056 V.)

QUANTITY: 1 drum, containing approximately 20,000 capsules, at St. Louis, Mo.
SHIPPED: 5-10-63, from Cincinnati, Ohio (a return shipment).

LABEL IN PART: "T.D. Pentaerythritol Tetranitrate Capsules Each Capsule Contains Pentaerythritol Tetranitrate 80 MG. * * * Mfg. for Queen City Pharm. Co. Manufactured by Shaw Pharmacal Co. * * * St. Louis 15, Mo."

LIBELED: 5-15-63, E. Dist. Mo.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drug.

DISPOSITION: 7-29-63. Default—destruction.

7502. Vasopred ophthalmic solution. (F.D.C. No. 49462. S. No. 12-397 X.)

QUANTITY: 464 5-cc. vials at Chicago, Ill.

SHIPPED: 9-5-63, from New Brunswick, N.J., by Smith, Miller & Patch, Inc.

LABEL IN PART: "New Formula Vasopred Ophthalmic Solution, Caution: * * * Composition: * * * Smith, Miller & Patch, Inc., New York, N.Y."

ACCOMPANYING LABELING: Inserts entitled "Vasopred New Formula Ophthalmic Solution."

LIBELED: 10-11-63, N. Dist. Ill.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 11-12-63. Default—destruction.

7503. Vasopred ophthalmic solution. (F.D.C. No. 49465. S. Nos. 64-772/3 X.)

QUANTITY: 1,338 5-cc. vials at Atlanta, Ga.

SHIPPED: 9-5-63 and 9-18-63, from New Brunswick, N.J., by Smith, Miller & Patch, Inc.

LABEL IN PART: "New Formula Vasopred * * * Caution * * * Smith, Miller & Patch, Inc., New York, N.Y."

ACCOMPANYING LABELING: Inserts entitled "Vasopred New Formula Ophthalmic Solution."

LIBELED: 10-14-63, N. Dist. Ga.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 11-26-63. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS AND DEVICES FOR HUMAN USE

7504. Amphetamine drugs. F.D.C. No. 48256. S. Nos. 6/9 V.)

QUANTITY: 4 50,000-tablet drums, unlabeled, at Greenville, S.C., in possession of Frank Albert Mays.

SHIPPED: On or prior to 10-25-62, from outside the State of South Carolina.

LIBELED: 10-25-62, W. Dist. S.C.

CHARGE: 502(f) (1)—while held for sale, the labeling failed to bear adequate directions for use and the drugs were not exempt from such requirement since they were in possession of a person who was not regularly and lawfully engaged in the manufacture, transportation, storage, or distribution of prescription drugs and since the articles were not to be dispensed upon prescription as required by regulations.

DISPOSITION: 4-19-63. Default—delivered to the Food and Drug Administration.

7505. Amphetamine tablets and capsules. (F.D.C. No. 48048. S. Nos. 2-601/4 V.)

QUANTITY: Unknown quantities of tablets and/or capsules containing amphetamine at Charleston, S.C., in possession of Wilburt Dennis and Hugh J. Ware.

SHIPPED: On unknown dates, from outside the State of South Carolina.

LIBELED: 9-28-62, E. Dist. S.C.

CHARGE: 502(f) (1)—while held for sale, the labeling of the article failed to bear adequate directions for use and the articles were not exempt from such requirement since they were in the possession of persons who were not regularly and lawfully engaged in the manufacture, transportation, storage, or distribution of prescription drugs and since such articles were not to be dispensed as required by regulations.

DISPOSITION: 3-16-63. Default—delivered to the Food and Drug Administration.

7506. Amphetamine sulfate tablets and caffeine tablets. (F.D.C. No. 48612. S. Nos. 881/2 V.)

QUANTITY: 32 1,000-tablet btls. of *amphetamine sulfate tablets* and 13 1,000-tablet btls. of *caffeine tablets*, at Miami, Fla., in possession of William G. Dexter and Leevy C. Mears.

SHIPPED: Prior to 1-16-63, from outside the State of Florida.

LIBELED: On or about 1-17-63, S. Dist. Fla.

CHARGE: 502(b)—while held for sale, the articles failed to bear labels containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents; 502(e)(1)—the articles failed to bear a label containing the common or usual name of the articles; 502(f)(1)—the labeling of the *amphetamine sulfate tablets* failed to bear adequate directions for use, and they were not exempt from such requirement since they were in possession of persons who were not regularly and lawfully engaged in the manufacture, transportation, storage, or distribution of prescription drugs and since the articles were not to be dispensed upon prescription, as prescribed by regulations; and 502(f)(1)—the labeling of the *caffeine tablets* failed to bear adequate directions for use.

DISPOSITION: 3-18-63. Default—delivered to the Food and Drug Administration.

7507. Pentobarbital sodium capsules, dextro-amphetamine sulfate tablets, methyltestosterone tablets, penicillin tablets, and penicillin G streptomycin aqueous solution. (F.D.C. No. 48695. S. Nos. 59-901/5 V.)

QUANTITY: 1 ctn. containing 1,000 capsules of *pentobarbital sodium*, 1,000 *dextro-amphetamine sulfate tablets*, 100 tablets of *methyltestosterone*, 100 200,000-unit tablets of *penicillin*, and 6 10-cc. vials of *penicillin G streptomycin aqueous solution*, at Lumber City, Ga.

SHIPPED: 3-28-62, from Philadelphia, Pa., by Columbia Pharmaceutical Co.

LABEL IN PART: (Ctn.) "Wooten Drug Co. Lumber City, Georgia from Columbia Pharmaceutical Co. Philadelphia, Pa."; (containers) "Pentobarbital Sodium 1½ gr.," "Dextro Amphetamine Sulfate," "Methyl Testosterone 25 mg.," "Penicillin G. Streptomycin Aqueous solution," and "Penicillin Tablets."

RESULTS OF INVESTIGATION: The articles purported to be prescription-restricted drugs which were delivered without prescription contrary to 503(b).

LIBELED: 2-8-63, S. Dist. Ga.

CHARGE: 502(f)(1)—when shipped, the labeling of the articles failed to bear adequate directions for use and the articles were not exempt from such requirement.

DISPOSITION: 3-19-63. Default—delivered to the Food and Drug Administration.

7508. Neo-Cobanate. (F.D.C. No. 49102. S. No. 66-214 V.)

QUANTITY: 5 boxes, each containing 12 5-cc. vials, at Hato Rey, P.R.

SHIPPED: 1-29-63, from Hialeah, Fla., by Delta Pharmaceuticals, Inc.

LABEL IN PART: (Vial) "Neo-Cobanate Each cc contains: Sodium Nicotinate 25 mg. Cryst. Vitamin B₁₂ 1000 mcg. * * * Dosage * * * Caution * * * Delta Pharmaceuticals, Inc., Miami, Florida."

ACCOMPANYING LABELING: Box insert entitled "Cobanate Neo-Cobanate For Relief of Pain of Neural Origin."

LIBELED: 7-6-63, Dist. P.R.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the treatment of trigeminal neuritis, tic doloreaux, peripheral neuritis, diabetic neuritis, herpes zoster, postherpetic neuralgia, tabetic crisis, neuritides in general, cephalalgia, migraine, malarial headache, sinus headache, and spinal tap cephalalgia; and that an article in the Journal of the American Medical Association, Volume 121, page 103, 1946, supported the use of the drug for the diseases and conditions for which the article was recommended; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use and it was not exempt from such requirements since its labeling failed to bear, as required by the exemption regulations for prescription drugs, adequate information for its use under which practitioners licensed to administer the drug could use the article safely and for the purposes for which it was intended.

DISPOSITION: 10-11-63. Default—destruction.

7509. Estomaryl. (F.D.C. No. 48843. S. No. 22-651 V.)

QUANTITY: 329 cases, each containing 25 5½-oz. btl., at Clovis, N. Mex., in possession of Estomaryl, Inc.

SHIPPED: 1-17-63, from El Paso, Tex.

LABEL IN PART: (Btl.) "Estomaryl For The Temporary Relief of Gastric Hyperacidity Due To Dietary Indiscretions * * * Manufactured by Laboratorios Imperiales, Mexico City D.F. * * * Active Ingredients * * * Warning * * * Caution."

ACCOMPANYING LABELING: Display placard reading in part "Estomaryl For Relief of Ulcer Pains and Nervous Stomach."

RESULTS OF INVESTIGATION: The display placard was prepared and printed on order of the dealer for the purpose of promoting sales of the article.

LIBELED: 4-9-63, Dist. N. Mex.; libel amended 4-12-63.

CHARGE: 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective as a treatment for conditions associated with ulcers and nervous stomach; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use for the conditions and purposes, namely, ulcers, nervous stomach, excessive gas, severe indigestion, and abdominal pains, for which it was offered in its labeling and in a local newspaper advertisement, since adequate directions for lay use cannot be written for such conditions and purposes.

DISPOSITION: 5-17-63. Consent—claimed by Estomaryl, Inc., of Clovis, N. Mex., and relabeled.

7510. Micro-Dynameter device. (F.D.C. No. 47688. S. No. 4-900 T.)

QUANTITY: 1 device at Washington, D.C.

SHIPPED: On or about 6-20-58, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "For Scientific Body Analysis * * * The Ellis Micro-Dynameter * * * Mfd. by Ellis Research Laboratories, Inc., Chicago."

ACCOMPANYING LABELING: Booklet entitled "A Practical Manual for Micro-Dynameter Model SA-2 * * * Copyright 1958 Ellis Research Laboratories, Inc., Chicago, U.S.A."

RESULTS OF INVESTIGATION: Examination indicated that the device was essentially a galvanometer for measuring electrical currents and electrical potentials of small magnitude. The device was mounted in a metal cabinet, on the face of which was a scale or meter intended to measure the flow of current in milliamperes, together with a number of dials which could be set at numbered or lettered positions. The dial settings were intended to increase or decrease the resistance to the current flowing through the device. The current which flowed and was measured by the scale or meter was generated by closing the circuit between two dissimilar metal "probes." The circuit was closed by placing the "probes" at different points on the human body, by placing the "probes" together, or by immersing them in water.

LIBELED: 6-21-62, Dist. Columbia.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective for diagnosing disease; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use, and it was not entitled to any exemption from that requirement.

DISPOSITION: 8-6-62. Default—delivered to the Food and Drug Administration.

7511. Micro-Dynameter device. (F.D.C. No. 47737. S. No. 70-307 T.)

QUANTITY: 1 device at Kasson, Minn.

SHIPPED: Between 5-1-58 and 6-30-58, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "The Ellis Micro-Dynameter * * * Mfd. by Ellis Research Laboratories, Inc., Chicago."

ACCOMPANYING LABELING: Booklet entitled "A Practical Manual for Micro-Dynameter Model SA-2 * * * Copyright 1958, Ellis Research Laboratories, Inc., Chicago"; and looseleaf binder containing various pieces of literature relating to the device, one of which was entitled "Bulletin of Micro-Dynameter Research Association * * * No. 4A, Sept., 1946. Mathematical Expression of Spinal Analysis with Micro-Dynameter," and one of which was entitled "Journal of Micro-Dynameter Research * * * No. J-4, Chiropractors Turn to Science."

LIBELED: 7-19-62, Dist. Minn.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective for diagnosing disease; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use, and it was not entitled to any exemption from that requirement.

DISPOSITION: 10-26-62. Default—delivered to the Food and Drug Administration.

7512. Micro-Dynameter devices (2 seizure actions). (F.D.C. Nos. 48311, 48506. S. Nos. 57-993 T; 16-338 V.)

QUANTITY: 2 devices, at Anderson and Boonville, Ind.

SHIPPED: Between 1-1-45 and 12-31-46, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "For Scientific Body Analysis The Ellis Micro-Dynameter Mfd. by Ellis Research Laboratories, Inc., Chicago U.S.A."

ACCOMPANYING LABELING: Looseleaf notebook containing literature pertaining to the device.

LIBELED: 10-17-62 and on or about 1-31-63, S. Dist. Ind.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for diagnosing disease; and 502(f) (1)—the labeling of the articles failed to bear adequate directions for use and they were not entitled to any exemption from that requirement.

DISPOSITION: 12-4-62; 3-26-63. Default—destruction.

7513. Micro-Dynameter devices (2 seizure actions). (F.D.C. Nos. 48362, 48389. S. Nos. 31-273 V, 15-861 V.)

QUANTITY: 2 devices, at Douglas, Ariz., and Eminence, Ky.

SHIPPED: Between 1-1-48 and 2-26-62, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "For Scientific Body Analysis The Ellis Micro-Dynameter Mfd. by Ellis Research Laboratories, Inc., Chicago U.S.A."

LIBELED: 11-28-62, E. Dist. Ky.; 12-11-62, Dist. Ariz.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for diagnosing disease; and 502(f) (1)—the labeling of the articles failed to bear adequate directions for use, and they were not entitled to any exemption from that requirement.

DISPOSITION: 2-27-63; 1-16-63. Default—delivered to the Food and Drug Administration.

7514. Auto-Electronic Radioclast device. (F.D.C. No. 48410. S. No. 16-460 T.)

QUANTITY: 1 device at White Bluff, Tenn.

SHIPPED: About 1940, from Tiffin, Ohio, by Electronic Instrument Co.

LABEL IN PART: (Control panel) "Auto-Electronic Radioclast, Model 20, series 800 Electronic Instrument Co., Tiffin, Ohio, USA" and (side panel) "Auto-Electronic Radioclast, Mfg. by Electronic Instrument Co., Tiffin, Ohio, Model 20, serial 831."

RESULTS OF INVESTIGATION: The article was a wood cabinet containing a combination of electronic circuits. The control panel contained pilot lights, line switch, heater switch, and a series of three dials intended for use in determining the identity of diseased organs. Three other dials purported to identify the disease conditions present, and additional dials determined the intensity of the disease conditions. The amount of current passing through the device was controlled by an intensity rheostat. A detector plate, as an attachment, purported to locate the point of maximum reaction and thus determine the location of the disease in the body.

LIBELED: 12-6-62, M. Dist. Tenn.

CHARGE: 502(f) (1)—when shipped, the labeling of the device failed to bear adequate directions for use.

DISPOSITION: 3-21-63. Default—destruction.

7515. Electro-Metabograph device. (F.D.C. No. 48672. S. No. 31-198 V.)

QUANTITY: 1 device at Los Angeles, Calif.

SHIPPED: In 1940 or 1941, from Detroit, Mich., by Art Tool & Die Co.

LABEL IN PART: (Metal plate on device) "Electro-Metabograph" and (meter on main panel) "Electro Metabograph Cardio Tachovolumeter Art Tool and Die Co., Detroit, Mich."

RESULTS OF INVESTIGATION: The article was a three-paneled, desk-type console unit. The panels contained a variety of push buttons, switches, dials, meters, and a photoelectric cell. One of the panels was an oscilloscope and controls. A small metal well which was for the blood sample was on the desk top. A probe-type electrode was also attached to the instrument for locating pinched nerves.

LIBELED: 1-16-63, S. Dist. Calif.; amended libel 1-22-63.

CHARGE: 502(f) (1)—when shipped and while held for sale, the labeling failed to bear adequate directions for use, and it was not entitled to any exemption from such requirement since the article was worthless for any diagnostic or therapeutic use.

DISPOSITION: 3-8-63. Default—destruction.

DRUG FOR VETERINARY USE

7515. Standard's Hog Mineral Preparation Medicated. (F.D.C. No. 49214. S. No. 29-295 V.)

QUANTITY: 11 50-lb. bags at Chadwick, Ill.

SHIPPED: 7-12-62 and 12-29-62, from Omaha, Nebr., by Standard Chemical Manufacturing Co.

LABEL IN PART: "Standards Hog Mineral Preparation Medicated * * * Active Drug Ingredient Arsanilic Acid 0.50% * * * Station B - Omaha, Nebraska * * * Standard Chemical Mfg. Company" or "Standard's with Arsanilic Acid Hog Mineral Preparation * * * Standard Chemical Mfg. Co. * * * Omaha, Nebr."

ACCOMPANYING LABELING: Inserts entitled "Standard's Hog Mineral Preparation Medicated" or "An Alfalfa Concentrate * * * 40% Concentrate without Alfalfa."

LIBELED: 8-2-63, N. Dist. Ill.

CHARGE: 502(f) (1)—when shipped, the labeling of the article failed to bear adequate directions for use; (5 bags only) 502(e) (2)—the label failed to declare the quantity of the active drug ingredient, arsanilic acid; and 502(f) (2)—the label failed to bear adequate warnings against use.

The libel alleged also that the article was adulterated under the provisions of the Act relating to foods, as reported in notices of judgment on foods.

DISPOSITION: 10-2-63. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF INSANITARY CONDITIONS

7517. Amphetamine compound capsules. (F.D.C. No. 48286. S. Nos. 52-412/13 T.)

QUANTITY: 1 btl. of about 700 capsules and 1 btl. of about 8,800 capsules, at Sandy, Oreg.

SHIPPED: 5-10-62 and 6-7-62, from Camden, N.J., by Philadelphia Laboratories.

LABEL IN PART: "Amphetamine Compound No. 15 [or "No. 30"] * * * Philadelphia Ampoule Laboratories Philadelphia 23, Pa."

RESULTS OF INVESTIGATION: Examination showed that the article was contaminated with lindane and chlordane.

LIBELED: On or about 11-16-62, Dist. Oreg.

CHARGE: 501(a)(2)—when shipped and while held for sale, the article had been prepared and packed under insanitary conditions whereby it may have been rendered injurious to health.

DISPOSITION: 12-19-62. Default—destruction.

7518. Nu-Life food supplement capsules. (F.D.C. No. 48100. S. No. 69-700 T.)

QUANTITY: 32 cases of 12 boxes each, each box containing 2 plastic bags, one bag containing 182 vitamin and mineral formula capsules and the other bag containing 546 amino acid with natural B complex tablets, at Washington, D.C.

SHIPPED: (Amino acid tablets) 8-25-61, from Long Island City, N.Y., by Nysco Laboratories, Inc., and (vitamin and mineral capsules) on an unknown date by an unknown shipper.

LABEL IN PART: (Box) "Nu-Life Dietary Food Supplement."

RESULTS OF INVESTIGATION: The article had been repacked into the above-mentioned boxes from bulk lots shipped as described above. Examination showed that the amino acid with natural B complex tablets were contaminated with lindane.

LIBELED: 9-11-62, Dist. Columbia.

CHARGE: 501(a)(2)—when shipped and while held for sale, the article had been prepared and packed under insanitary conditions whereby it may have been rendered injurious to health.

DISPOSITION: 11-2-62. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

7519. Posterior pituitary injection. (F.D.C. No. 48611. S. No. 18-276 V.)

QUANTITY: 50 ctnd. vials at Houston, Tex.

SHIPPED: 10-5-62, from Chicago, Ill.

LABEL IN PART: (Ctn.) "No. 156 10 cc. Vial Posterior Pituitary 20 U.S.P. units Each cc. contains: Posterior Pituitary Extract 20 U.S.P. Units."

RESULTS OF INVESTIGATION: Analysis showed that the potency of the article was substantially less than 20 U.S.P. posterior pituitary units per cubic centimeter.

LIBELED: 1-16-63, S. Dist. Tex.

CHARGE: 501(b)—while held for sale, the strength of the article differed from the standard for posterior pituitary set forth in the United States Pharmacopeia; and 502(a)—the label statement "Each cc. contains: Posterior Pituitary Extract 20 U.S.P. Units" was false and misleading.

DISPOSITION: 3-6-63. Default—destruction.

7520. Digitalis tablets. (F.D.C. No. 48388. S. No. 74-247 T.)

QUANTITY: 7 5,000-tablet cans at Brooklyn, N.Y.

SHIPPED: 2-20-62, from Hoboken, N.J.

RESULTS OF INVESTIGATION: Analysis showed that the article contained not more than 74.6 percent of the declared amount of digitalis.

LIBELED: 12-7-62, E. Dist. N.Y.

CHARGE: 501(b)—while held for sale, the strength of the article differed from the standard for *digitalis tablets* set forth in the United States Pharmacopeia; 502(a)—the label statement "1½ (0.1 gm.)" was false and misleading as applied to a product containing less than the declared amount of digitalis.

DISPOSITION: 2-7-63. Default—destruction.

7521. Rubber prophylactics. (F.D.C. No. 48940. S. No. 69-004 V.)

QUANTITY: 190 ctns., each containing 72 pkgs. of 2 units each, at Baltimore, Md.

SHIPPED: 4-12-63, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Crown Brand Prophylactics * * * Distributed by Parkway Mach. Corp. Baltimore 2, Md. * * * Sold for the prevention of disease only."

RESULTS OF INVESTIGATION: Examination showed that 1.2 percent of the 260 units examined were defective in that they contained holes.

LIBELED: 5-1-63, Dist. Md.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "Sold for the prevention of disease only" was false and misleading.

DISPOSITION: 6-3-63. Default—destruction.

7522. Rubber prophylactics. (F.D.C. No. 48966. S. No. 14-675 V.)

QUANTITY: 192 ctns., each containing 48 pkgs. of 3 units each, at Chicago, Ill.

SHIPPED: 10-11-62, from Newark, N.J., by Circle Rubber Corp.

LABEL IN PART: (Pkg.) "Slick Super Thin Prophylactics United Distributing Co. Chicago 45, Ill. * * * Sold For The Prevention of Disease Only."

RESULTS OF INVESTIGATION: Examination showed that 1.4 percent of the article examined was defective in that it contained holes.

LIBELED: 5-17-63, N. Dist. Ill.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "Sold for the prevention of disease only" was false and misleading.

DISPOSITION: 7-9-63. Default—destruction.

7523. Rubber prophylactics. (F.D.C. No. 49023. S. No. 24-184 X.)

QUANTITY: 19 gross in pkgs. of 31 each, 23 gross in pkgs. of 12 each, and 10 gross in pkgs. of 3 each, at Grand Rapids, Mich.

SHIPPED: 4-2-63 and 5-29-63, from Cleveland, Ohio, by Schaeffer Products Co.

LABEL IN PART: (Pkg.) "Frat House Rolled Prophylactics Packed by Schaeffer Products Co. Cleveland, Ohio * * * Sold Only to prevent disease [or "Assists in protecting health through the prevention of venereal disease and the reinfection of the female with *Trichomonas*"]."

RESULTS OF INVESTIGATION: Examination showed that 1.3 percent of the 228 units examined were defective in that they contained holes.

LIBELED: 6-28-63, W. Dist. Mich.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess.

DISPOSITION: 7-23-63. Consent—destruction.

7524. Rubber prophylactics. (F.D.C. No. 48861. S. No. 73-888 V.)

QUANTITY: 28 ctns., each containing 72 pkgs. of 2 units each, at Dallas, Tex.

SHIPPED: 3-1-63, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Spartans Prophylactics * * * M & M Rubber Co., Kansas City 8, Mo. * * * Sold For The Prevention of Disease Only."

RESULTS OF INVESTIGATION: Examination of 144 prophylactics showed that 2.08 percent were defective in that they contained holes.

LIBELED: On or about 5-6-63, N. Dist. Tex.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "Sold For The Prevention of Disease Only" was false and misleading.

DISPOSITION: 8-6-63. Default—destruction.

7525. Rubber prophylactics. (F.D.C. No. 49042. S. No. 38-521 X.)

QUANTITY: 85 ctns., each containing 48 pkgs. of 3 units each, at Florence, Ala.

SHIPPED: 5-14-63, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Three Super Thin Viking Transparent Prophylactics M&M Rubber Co. Kansas City, 8, Mo. Sold for the prevention of disease."

RESULTS OF INVESTIGATION: Examination showed that 3.4 percent of the 87 prophylactics examined were defective in that they contained holes.

LIBELED: 7-12-63, N. Dist. Ala.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "Sold For the Prevention of Disease" was false and misleading.

DISPOSITION: 8-12-63. Default—destruction.

7526. Rubber prophylactics. (F.D.C. No. 49081. S. No. 68-950 V.)

QUANTITY: 40 ctns., each containing 72 pkgs. of 1 unit each, at Baltimore, Md.

SHIPPED: 1-21-63, from Newark, N.J., by Circle Rubber Corp.

LABEL IN PART: (Pkg.) "Lubra Pak Saxon Micro-Thin Transparent Prophylactic * * * Manufactured by Circle Rubber Corp., Newark, N.J., and (unit) "Sold For Prevention of Disease Only."

RESULTS OF INVESTIGATION: Examination showed that 4.2 percent of the 72 units examined were defective in that they contained holes.

LIBELED: 6-17-63, Dist. Md.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "Sold For Prevention of Disease Only" was false and misleading.

DISPOSITION: 8-27-63. Default—destruction.

7527. Rubber prophylactics. (F.D.C. No. 49199. S. No. 27-343 X.)

QUANTITY: 1 case, containing 25 ctns., each containing 72 pkgs. of 3 units each, at Gainesville, Ga.

SHIPPED: 6-28-63, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Viking Prophylactics * * * Super Thin * * * M&M Rubber Co., K.C. 8, Mo. Sold For The Prevention of Disease Only."

RESULTS OF INVESTIGATION: Examination of 283 prophylactics showed that 1.41 percent were defective in that they contained holes.

LIBELED: 7-29-63, N. Dist. Ga.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "Sold For the Prevention of Disease Only" was false and misleading.

DISPOSITION: 8-28-63. Default—destruction.

7528. Rubber prophylactics. (F.D.C. No. 49054. S. No. 27-341 X.)

QUANTITY: 4 cases, each containing 25 boxes of 48 vials of 3 units each, at Hot Springs, Ark.

SHIPPED: 6-28-63, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Vial) "Sold for the prevention of disease only 3 Transparent prophylactics Swan Super Thin Reservoir Dist. By M & M Rubber Co. Kansas City, Mo."

RESULTS OF INVESTIGATION: Examination of 281 prophylactics showed that 1.06 percent were defective in that they contained holes.

LIBELED: 7-25-63, W. Dist. Ark.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "Sold For The Prevention Of Disease Only" was false and misleading.

DISPOSITION: 9-11-63. Default—destruction.

7529. Rubber prophylactics. (F.D.C. No. 49475. S. No. 4-348 X.)

QUANTITY: 57 ctns., each containing 72 pkgs. of 2 units each, at Baltimore, Md.

SHIPPED: 9-25-63, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Crown Brand Prophylactics * * * Distributed by Parkway Mach. Corp. Baltimore 2, Md. * * * Sold For The Prevention of Disease Only."

RESULTS OF INVESTIGATION: Examination showed that 3.3 percent of the 120 prophylactics examined were defective in that they contained holes.

LIBELED: 10-17-63, Dist. Md.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "Sold For The Prevention of Disease Only" was false and misleading.

DISPOSITION: 11-21-63. Default—destruction.

7530. Rubber prophylactics. (F.D.C. No. 49486. S. Nos. 12-900 X, 86-661 X.)

QUANTITY: 73 ctns., each containing 144 units, at Chicago, Ill.

SHIPPED: 7-20-62, from Newark, N.J., by Circle Rubber Corp.

LABEL IN PART: (Ctn.) "Protex Gold Piece * * * Prophylactics * * * A Product of National Sanitary Laboratories, Inc., Chicago 45, Illinois * * * Intended For Prevention Of Disease Only," (foil wrapper) "One Latex Transparent Prophylactic * * * National Sanitary Labs., Inc. Chicago, Ill. * * * For The Prevention of Disease," and (unit) "Sold For Prevention of Disease Only."

RESULTS OF INVESTIGATION: Examination showed that 1.3 percent of the 228 prophylactics examined were defective in that they contained holes.

LIBELED: 10-25-63, N. Dist. Ill.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; 502(a)—the label statements "Intended For Prevention Of Disease Only," "Sold For The Prevention Of Disease," and "Sold For Prevention of Disease Only" were false and misleading; and 502(a) the article was represented as being a product of National Sanitary Laboratories, Inc., which was false and misleading since that corporation was not the manufacturer.

DISPOSITION: 12-2-63. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MIS-LEADING CLAIMS*

7531. Cod liver oil. (F.D.C. No. 48383. S. Nos. 39-908/10 V.)

QUANTITY: 2 bulk drums; 25 cases, 6 doz. 1-oz. btl. each; 29 cases, 3 doz. 2-oz. btl. each; 51 cases, 3 doz. 4-oz. btl. each; and 29 cases, 2 doz. 8-oz. btl. each, at Hato Rey, P.R., in possession of Mendez Laboratories of America, Inc.

SHIPPED: 6-13-62, from Bergen, Norway.

LABEL IN PART: (Drum) Translated from Spanish "Cod Liver Oil With certified color [or "Cod Liver Oil U.S.P."]. Each 5 cc contains: Vitamin A 4250 Units and Vitamin D 425 Units * * * Mendez Laboratories of America, Inc. San Juan, Puerto Rico."

RESULTS OF INVESTIGATION: The article in the bottles was repacked from bulk drums by the dealer.

LIBELED: 11-29-62, Dist. P.R.

CHARGE: 502(a)—while held for sale, the labeling of the article in the drums and bottles contained false and misleading representations that the article was adequate and effective for the treatment and prevention of colds, bronchitis, and influenza; and to promote the development of bones and strong teeth.

The article in the bottles was alleged also to be (some bottles) adulterated and (all bottles) misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 3-12-63. Consent—claimed by Mendez Laboratories of America, Inc., and released under bond for the purpose of destroying the adulterated material and relabeling the material which was not adulterated but was misbranded.

7532. Apinol pine oil. (F.D.C. No. 48953. S. No. 59-348 V.)

QUANTITY: 300 2-oz. btl. and 72 4-oz. btl., at Greensboro, N.C., in possession of the Apinol Corp.

SHIPPED: 2-15-63, from Pensacola, Fla.

LABEL IN PART: (Btl.) "Apinol The Pine Antiseptic Distributed by The Apinol Corp., Greensboro, N.C. * * * Active Ingredient: Pine Oil."

RESULTS OF INVESTIGATION: The article was shipped, as described above, in bulk drums and after receipt by the Apinol Corp. was repacked into the bottles described above.

LIBELED: 5-13-63, M. Dist. N.C.

CHARGE: 502(a)—while held for sale, the label of the article contained false and misleading representations that the article was adequate and effective as

*See also Nos. 7508-7513, 7519-7522.

a healing treatment for minor injuries, cuts, bruises, superficial burns, abrasions, sunburn, ringworm, athlete's foot, toothache, and sore throat.

DISPOSITION: 6-29-63. Consent—destruction.

7533. Slim-O-Tabs tablets. (F.D.C. No. 48854. S. Nos. 58-871/2 V.)

QUANTITY: 14 50-tablet btl.s. and 29 100-tablet btl.s., at Atlantic City, N.J.

SHIPPED: 8-5-62 and 2-20-63, from Philadelphia, Pa., by Jan Laboratories.

LABEL IN PART: (Btl.) "Slim-O-Tabs (Phenylpropanolamine HCl Tablets 25 Mg.) Trim Pounds - Slim Lines For Appetite Control Dose: 1 tablet 3 times a day Distributed by Lincoln Pharmacy, Inc. * * * Atlantic City, N.J."

LIBELED: 4-24-63, Dist. N.J.

CHARGE: 502(a)—when shipped, the name of the article and representations in its labeling that the article was adequate and effective for weight reduction and for figure and appetite control were false and misleading.

DISPOSITION: 6-7-63. Default—destruction.

7534. Visol tonic. (F.D.C. No. 48589. S. No. 40-237 V.)

QUANTITY: 140 btl.s. at Newark, N.J.

SHIPPED: 5-3-62, from Santurce, P.R., by Rifer Laboratories, Inc.

LABEL IN PART: (Btl.) "Visol Strengthens Vision And Brain * * * 8 Fl. Oz. Each 15 cc (1 spoonful) contains: Vitamin 'A' (Palmitate) 10,000 U.; Vitamin 'B-1' 10 mgm.; Calcium Glycerophosphate 50 mgm. * * * Dose * * * Rifer Laboratories, Inc. Santurce, Puerto Rico."

LIBELED: 1-7-63, Dist. N.J.

CHARGE: 502(a)—when shipped, the bottle label contained false and misleading representations that the article was adequate and effective to strengthen vision and brain; and for the treatment and prevention of loss of eye brightness, infection of the mucosa, and dryness of the skin.

DISPOSITION: 2-14-63. Default—destruction.

7535. Swiss whey powder. (F.D.C. No. 48750. S. No. 23-510 V.)

QUANTITY: 13 cases, 12 1-lb. cans each and 1 case, 4 5-lb. cans each, at Glendale, Calif.

SHIPPED: 3-26-63, from Tremonton, Utah, by Whey Products Co.

LABEL IN PART: (Can) "SPRAY DRIED POWDER SWISS WHEY * * * Packed exclusively by Whey Products Company, Box 366, Tremonton, Utah."

LIBELED: 4-18-63, S. Dist. Calif.

CHARGE: 502(a)—when shipped, the label bore false and misleading representations that the article was adequate and effective to promote health, promote the growth of friendly bacteria in the system, neutralize stomach acid, and promote digestion; that the article supplied unusually high nutrition in an amount which was low in calories; and that the article contained the milk sugar (lactose), protein, calcium, phosphorus, and vitamins of whole milk.

DISPOSITION: 5-29-63. Default—destruction.

7536. Abunda Beauty device. (F.D.C. No. 46667. S. No. 68-643 R.)

INFORMATION FILED: 11-7-62, N. Dist. Calif., against Abunda Products, Inc., San Mateo, Calif., and Joseph Ruffino, president.

SHIPPED: 11-7-60 and 11-22-60, from Menlo Park, Calif., to Fort Worth, Tex.

LABEL IN PART: (Ctn.) "Abunda Beauty by Abunda Products * * * San Mateo, California."

ACCOMPANYING LABELING: Pamphlets entitled "Abunda Beauty . . . New . . . Exciting . . . Revolutionary" and "Abunda Hydro Massage Bosom Beauty."

CHARGE: 502(a)—when shipped, the name "*Abunda Beauty*" and statements in the accompanying labeling were false and misleading in that they represented and suggested that the device was adequate and effective for awakening and increasing bosom beauty; encouraging bosom perfection; restoring, healing, and revitalizing the tissues of the bosom; increasing circulation of the bust; providing cell nourishment to firm the tissues; and for providing an abundant bust through hydrotherapy.

PLEA: Nolo contendere.

DISPOSITION: 8-5-63. Individual—30 days imprisonment, probation for 5 years, and \$500 fine; corporation—\$1 fine.

7537. Bioelectrometer device. (F.D.C. No. 48085. S. No. 31-712 T.)

QUANTITY: 3 devices at San Diego, Calif.

SHIPPED: 2-16-62, from St. Louis, Mo., by Cansi Electronics, Ltd.

LABEL IN PART: "BIOELECTROMETER Electrophysical Resistance Instrument Cansi Electronics, Ltd., Saint Louis Missouri."

ACCOMPANYING LABELING: Booklet entitled "Operating Instructions for the Bioelectrometer"; and leaflets entitled "Special Instructions for using the New 1961 Model EPR-19 Bioelectrometer," "Instructions for the use of the Bioelectrometer," and "New Bioelectronic Aid in Clinical Diagnosis."

RESULTS OF INVESTIGATION: Examination indicated that the article was a metal instrument cabinet containing a power supply and circuitry which provided a voltage between a probe and a hand electrode. The amount of current passing between these two elements was indicated by a microammeter on the instrument control panel.

LIBELED: 9-6-62, S. Dist. Calif.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective in measuring the variations in the electrical sensitivity of the human body, thereby serving as a diagnostic aid in determining the presence of general toxicity and the need for further X-ray and laboratory study; in detecting organic pathology, spinal lesions, glandular malfunction, visceral pathology, and subacute visceral inflammation.

DISPOSITION: 10-8-62. Default—delivered to the Food and Drug Administration.

7538. Rejuvené device. (F.D.C. No. 48651. S. No. 28-246 V.)

QUANTITY: 26 devices, each accompanied by 1 btl. of lotion, at Des Moines, Iowa.

SHIPPED: During October 1960, from Minneapolis, Minn., by Rejuvené, Inc.

LABEL IN PART: (Device) "Rejuvené"; (btl.) "Rejuvené Lotion."

ACCOMPANYING LABELING: Leaflets and pamphlets entitled "For Your Face of the Future! Rejuvené"; leaflets and placards entitled "Does Your Face Show Your Age"; and leaflets entitled "Rejuvené Product Knowledge" and "Technical Data."

RESULTS OF INVESTIGATION: The device was battery-operated, transistorized, electrical pulse generator and associated electrode applicator enclosed in a plastic case.

LIBELED: 2-27-63, S. Dist. Iowa.

CHARGE: 502(a)—when shipped, the name "*Rejuvené*" and statements in the labeling represented that the article was adequate and effective for regaining and retaining a youthful face and throat by overcoming lines and wrinkles in the area of the forehead, eyes, nose, mouth, chin, neck and throat by toning and firming sagging and weakened muscles and facial skin tissues, which name and representations were false and misleading, since the article was not adequate and effective for such purposes.

DISPOSITION: 4-22-63. Default—delivered to the Food and Drug Administration.

7539. Whirlpool Geyser Bath device. (F.D.C. No. 47728. S. No. 53-139 T.)

QUANTITY: 77 devices, each in a display-type ctn., at Milton, Wash.

SHIPPED: Between 3-15-62 and 4-13-62, from Oconomowoc, Wis., by Sholin Manufacturing Corp.

LABEL IN PART: (Ctn.) "Whirlpool Geyser Bath * * * Your Very Own Trained Masseur."

ACCOMPANYING LABELING: Carton insert "Instructions for Geyser Bath."

RESULTS OF INVESTIGATION: Examination showed the device to be a large plastic tube, about 4 feet by 9 inches in length, with a fitting for a vacuum cleaner at one end and a simple valve fitting at the other end, connected to two smaller hoses. The smaller hoses were about 5 feet in length, capped at one end and having holes bored at 3-inch intervals for the length of the hose. The smaller hoses and the valve were also fitted with suction cups.

LIBELED: 7-12-62, W. Dist. Wash.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was adequate and effective as a treatment for the relief of gout, arthritis, cuts and breaks, sprains, cerebral palsy, overweight, bruises, polio, rheumatism, indigestion nerves, multiple sclerosis, sore muscles, and tired, aching feet.

DISPOSITION: 3-25-63. Default—destruction.

7540. Aqua-Laxer Hydro-Massage device. (F.D.C. No. 47972. S. No. 50-856 T.)

QUANTITY: 57 devices at San Jose, Calif.

SHIPPED: Between 2-9-62 and 7-8-62, from Seattle, Wash., by Aqua-Laxer Manufacturing Corp.

LABEL IN PART: "Aqua-Laxer Mfg. by Aqua-Laxer Mfg. Corp. * * * Seattle 3, Wash."

ACCOMPANYING LABELING: Brochure entitled "Aqua-Laxer Hydro-Therapy Massage"; manual entitled "Presentation for Aqua-Laxer"; green manila folder containing a visual-aid set entitled "Aqua-Laxer," a guarantee, and copies of advertisements run in local newspapers and in a Houston, Tex., newspaper.

RESULTS OF INVESTIGATION: Investigation indicated that the device consisted of a perforated plastic mat, a flexible hose, and a motor-driven air blower which produced a flow of air bubbles in bath water.

LIBELED: 8-15-62, N. Dist. Calif.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective as a treatment for nervous tension, poor circulation, muscle spasm, muscle tension, fatigue, arthritis, rheumatism, bursitis, to induce sleep, varicose veins, back-ache, insomnia, chills, and polio.

DISPOSITION: 9-27-62. Consent—claimed by Aqua-Laxer Manufacturing Corp.
 Ordered released for the purpose of salvaging by bringing the article into compliance with the law.

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PRODUCTS

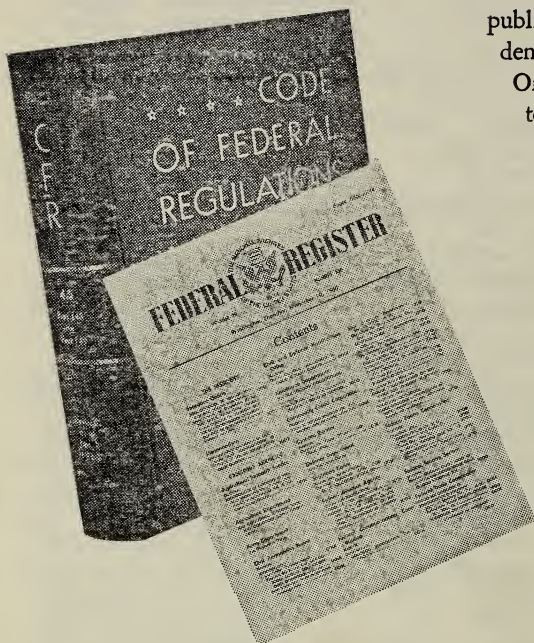
	N.J. No.		N.J. No.
Abunda Beauty device-----	7536	Neuralgia, remedies for. <i>See</i>	
Amphetamine capsules and tablets -----	7505	Rheumatism, remedies for.	
compound capsules-----	7517	Neuritis, remedies for. <i>See</i>	
dextro-, sulfate tablets-----	7507	Rheumatism, remedies for.	
drugs -----	7504	Nu-Life food supplement capsules -----	7518
sulfate tablets-----	7506	Obesity, remedy for. <i>See</i> Reducing preparation.	
Androgenic substance-----	7507	Ophthalmic solution, Vasopred--	7502, 7503
Apinol pine oil-----	7532	Penicillin G streptomycin aqueous solution-----	7507
Aqua-Laxer Hydro-Massage device -----	7540	tablets -----	7507
Arthritis, remedies for. <i>See</i>		Pentaerythritol tetranitrate capsules -----	7501
Rheumatism, remedies for.		Pentobarbital sodium capsules--	7507
Auto-Electronic Radioclast device -----	7514	Pine oil, Apinol-----	7532
Bioelectrometer device-----	7537	Pituitary, posterior, injection--	7519
Bursitis, remedies for. <i>See</i>		Posterior pituitary injection--	7519
Rheumatism, remedies for.		Prophylactics, rubber-----	7521-7530
Caffeine tablets-----	7506	Reducing preparation-----	7533
Cod liver oil-----	7531	Rejuvené device-----	7538
Cosmetic (subject to the drug provisions of the Act)-----	7538	Rheumatism, remedies for (devices) -----	7539, 7540
Devices ----- 7510-7515, 7521-7530, 7536-7540		Slim-O-Tabs tablets-----	7533
Dextro-amphetamine sulfate tablets -----	7507	Standard's Hog Mineral Preparation Medicated-----	7516
Digitalis tablets-----	7520	Stomach disorders, remedy for--	7509
Electro-Metabograph device-----	7515	Swiss whey powder-----	7535
Estomaryl -----	7509	Tonic, Visol-----	7534
Gout, remedies for. <i>See</i> Rheumatism, remedies for.		Vasopred ophthalmic solution-----	7502, 7503
Hog Mineral Preparation Medicated, Standard's-----	7516	Veterinary preparation-----	7516
Methyltestosterone tablets-----	7507	Visol tonic-----	7534
Micro-Dynameter devices--- 7510-7513		Whey powder, Swiss-----	7535
Neo-Cobanate -----	7508	Whirlpool Geyser Bath device---	7539

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

	N.J. No.		N.J. No.
Abunda Products, Inc.:		Aqua-Laxer Manufacturing Corp.:	
Abunda Beauty device-----	7536	Aqua-Laxer Hydro-Massage device -----	7540
Apinol Corp.:			
Apinol pine oil-----	7532		

	N.J. No.		N.J. No.
Art Tool & Die Co.:		Nysco Laboratories, Inc.:	
Electro-Metabograph device----	7515	Nu-Life food supplement capsules -----	7518
Cansi Electronics, Ltd.:		Parkway Machine Corp.:	
Bioelectrometer device-----	7537	rubber prophylactics-----	7521, 7529
Circle Rubber Corp.:		Philadelphia Ampoule Laboratories:	
rubber prophylactics_	7522, 7526, 7530	amphetamine compound capsules -----	7517
Columbia Pharmaceutical Co.:		Philadelphia Laboratories:	
pentobarbital sodium capsules, dextro-amphetamine sulfate tablets, methyltestosterone tablets, penicillin tablets, and penicillin G streptomycin aqueous solution-----	7507	amphetamine compound capsules -----	7517
Delta Pharmaceuticals, Inc.:		Queen City Pharmacal Co.:	
Neo-Cobanate -----	7508	pentaerythritol tetranitrate capsules -----	7501
Dennis, Wilburt:		Rejuvené, Inc.:	
amphetamine capsules and tablets -----	7505	Rejuvené device-----	7538
Dexter, W. G.:		Rifer Laboratories, Inc.:	
amphetamine sulfate tablets and caffeine tablets-----	7506	Visol tonic-----	7534
Electronic Instrument Co.:		Ruffino, Joseph:	
Auto-Electronic Radioclast device -----	7514	Abunda Beauty device-----	7536
Ellis Research Laboratories, Inc.:		Schaeffer Products Co.:	
Micro-Dynameter devices_	7510-7513	rubber prophylactics-----	7523
Estomaryl, Inc.:		Shaw Pharmacal Co.:	
Estomaryl -----	7509	pentaerythritol tetranitrate capsules -----	7501
Jan Laboratories:		Sholin Manufacturing Corp.:	
Slim-O-Tabs tablets-----	7533	Whirlpool Geyser Bath device_	7539
Laboratorios Imperiales:		Smith, Miller & Patch, Inc.:	
Estomaryl -----	7509	Vasopred ophthalmic solution -----	7502, 7503
Lincoln Pharmacy, Inc.:		Standard Chemical Manufacturing Co.:	
Slim-O-Tabs tablets-----	7533	Standard's Hog Mineral Preparation Medicated-----	7516
M & M Rubber Co.:		United Distributing Co.:	
rubber prophylactics-----	7521, 7524, 7525, 7527-7529	rubber prophylactics-----	7522
Mays, F. A.:		Ware, H. J.:	
amphetamine drugs-----	7504	amphetamine capsules and tablets -----	7505
Mears, L. C.:		Whey Products Co.:	
amphetamine sulfate tablets and caffeine tablets-----	7506	Swiss whey powder-----	7535
Mendez Laboratories of America, Inc.:		Wooten Drug Co.:	
cod liver oil-----	7531	pentobarbital sodium capsules, dextro-amphetamine sulfate tablets, methyltestosterone tablets, penicillin tablets, and penicillin G streptomycin aqueous solution-----	7507
National Sanitary Laboratories, Inc.:			
rubber prophylactics-----	7530		

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U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

U. S. DEPT. OF AGRICULTURE

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NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD,
DRUG, AND COSMETIC ACT

AUG 24 1964

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

7541-7600

CURRENT SERIAL RECORDS

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were alleged to be adulterated or misbranded, or otherwise violative of the Act, when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent, and in which, in one case, a decree of dismissal was sustained upon appeal; (2) criminal proceedings which were terminated upon pleas of guilty or nolo contendere, and in which, in one case, was terminated, after trial by the court, upon a conviction for criminal contempt; and (3) injunction proceedings in which decrees of permanent injunction were entered and involving, in one case, criminal contempt and probation violation proceedings. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., June 12, 1964

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*For drugs in violation of prescription labeling requirements, see Nos. 7542, 7543, 7556; presence of a habit-forming substance without warning statements, No. 7543; contains, for purposes of coloring only, a color additive which is unsafe, No. 7562; omission of, or unsatisfactory, ingredients statements, Nos. 7541-7543, 7556-7559, 7561, 7564, 7596; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 7563; cosmetics actionable under the drug provisions of the Act, Nos. 7562-7564.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN ALLEGED VIOLATIONS REPORTED IN D.D.N.J. NOS. 7541-7600

Adulteration, Section 501(a) (2), the article had been prepared and packed under insanitary conditions whereby it may have been rendered injurious to health; Section 501(a) (4) (A), the article was a drug which contained, for purposes of coloring only, a color additive which was unsafe within the meaning of Section 706(a); Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (National Formulary), and its strength differed from the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; Section 501(d) (2), the article was a drug, and a substance had been substituted wholly or in part therefor; and Section 706(a), a color additive was deemed to be unsafe because there was not in effect, a regulation listing such additive for a particular use, and such additive was neither from a batch certified for such use, nor had, with respect to such use, been exempted from certification.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents in terms of weight, measure, or numerical count; Section 502(c), a word, statement, or other information required by, or under authority of, the Act to appear on the label or labeling of the article was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(d), the article was for use by man, and contained a quantity of a chemical derivative of barbituric acid, which derivative had been found to be, and by regulation designated as, habit forming, and its label failed to bear the name, and quantity or proportion of such derivative and, in juxtaposition therewith, the statement "Warning - May be habit forming"; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient contained therein; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i) (2), the article was an imitation of another drug; Section 502(i) (3), the article was offered for sale under the name of another drug; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; Section 502(l), the article was composed wholly or in part of a kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or some derivative thereof, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; Section 503(b) (1), the article was a drug intended for use by man which was a habit-forming drug to which Section 502(d) applied, or because of its toxicity or other potentiality for harmful effect, or the collateral measures necessary to its use, was not safe for use except under the super-

vision of a practitioner licensed by law to administer such drug or was limited by an approved or effective application under Section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug, and it was dispensed contrary to the dispensing provisions of this Section; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application, or an approval of an application, filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUG AND DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

7541. Drug for injection represented by names of "Koch Treatment," "Glyoxylide," and "Koch's Glyoxylide," and device consisting of hypodermic syringe and needle. (Inj. No. 396.)

COMPLAINT FOR INJUNCTION FILED: 12-30-60, E. Dist. Tex., against Thomas Troupe Gammage Reynolds (son), Regina G. Reynolds (daughter-in-law), and Mattie Gammage Reynolds (mother), t/a Reynolds Clinic, Palestine, Tex.

NATURE OF BUSINESS: The defendants were engaged in the business of selling and distributing an article of drug which consisted of a clear liquid in glass ampules and an article of device which consisted of a hypodermic syringe and needle; said drug was designated by the names "*Koch Treatment*," "*Glyoxylide*," and "*Koch's Glyoxylide*." The labeling of the drug represented that the drug consisted of a one to a trillion dilution of the "Crystal Salt of Glyoxylide" in triple-distilled water; that the structural chemical formula of "*Glyoxylide*" was $O=C=C=O$; and that the drug was to be administered by injection. The labeling of the device represented that it was for use in the administration of the drug.

In carrying on their business, the defendants employed essentially the following method of operations:

(a) Various quantities of the drug and device were shipped from time to time in interstate commerce, into the State of Texas from places outside thereof, and, thereafter, were received by the defendants at Palestine, Tex.;

(b) Following the receipt of the drug and device, and while they were held for sale by the defendants at Palestine, Tex., the defendants caused the drug and device to be accompanied by labeling consisting of mimeographed leaflets entitled "The Reynolds Clinic * * * Since 1941," "Koch's Glyoxylide 12X," "The Koch Treatment (Glyoxylide) * * * 3. Arthritis," "The Koch Treatment (Glyoxylide) * * * 2. Bursitis," "The Koch Treatment (Glyoxylide) * * * 1. Alcoholic Neuritis," "Order Form," and "Glyoxylide 12X Sterile * * * $O=C=C=O$ "; a four-page mimeographed brochure entitled "Glyoxylide Case Reports"; and a four-page mimeographed brochure entitled "The Koch Treatment Patients Diet."

(c) The defendants promoted the sale of the drug and device by placing advertisements in various publications; one of the advertisements appeared in the August 1960 issue of the Defender Magazine published in Wichita, Kans., and read in part as follows: "Double treatment package, \$25.00. The Koch Treatment (Glyoxylide) Treat for results in carcinoma, sarcoma, leukemia, Hodgkins' Disease, and Arthritis. 40 Years in Use. Order from the Reynolds Clinic, Palestine, Texas * * *";

(d) The defendants further promoted the sale of the drug and device by transmitting copies of one or more pieces of the above labeling to prospective customers.

(e) Upon the receipt of orders for the drug and device, the defendants caused a package containing the drug and device, and, in some instances, one or more pieces of the labeling, to be prepared for shipment and transmitted to the purchasers via United States mail.

CHARGE: The complaint alleged that the drug, when sold and distributed by the defendants, was adulterated within the meaning of 501(c) in that the strength of the drug differed from that which it was represented to possess as the drug was represented to contain *Glyoxylyde*, whereas, it did not contain *Glyoxylyde*, and that the drug, when sold and distributed, was misbranded as follows: 502(a)—in that the labeling of the drug, namely, the above leaflets and brochures accompanying the drug, contained statements which represented, suggested, and implied that the drug contained *Glyoxylyde*, and that the drug was adequate and effective in the treatment and prevention of cancer and other diseases and conditions in man, which statements were false and misleading as the drug did not contain *Glyoxylyde* and was not adequate and effective in the treatment and prevention of cancer and other diseases and conditions in man; 502(b)—in that the drug was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e) (1)—in that the label of the drug failed to bear the common or usual name of the drug, namely, distilled water; 502(f) (1)—in that the labeling of the drug failed to bear adequate directions for use as the directions for use, with respect to dosage and frequency and duration of administration of the drug, appearing in the labeling of the drug were not adequate for the treatment and prevention of the diseases and conditions for which the drug was intended, including, in particular, cancer, since the drug was worthless for the treatment and prevention of cancer and any other disease or condition in man, and adequate directions could not be given for the use of such drug in the treatment and prevention of cancer and any other disease or condition in man; 502(f) (1)—in that the labeling of the drug failed to bear adequate directions for use as the drug was intended for unsupervised lay-use for injection, and adequate directions cannot be written for unsupervised lay-use of the drug for injection; 502(f) (2)—in that the labeling of the drug failed to bear adequate warnings against use for injection in those pathological conditions where its use may be dangerous to health and against unsafe methods of administration by injection; and 502(j)—in that the drug was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, the drug was dangerous for unsupervised lay-use for injection, and the directions in the labeling of the drug, with respect to the dosage, frequency, and duration of use for the drug, prescribed, recommended, and suggested the unsupervised lay-use of such drug for injection.

The complaint alleged also that the device, when sold and distributed, was misbranded as follows: 502(f) (1)—in that the labeling of the device failed to bear adequate directions for use as the device was intended for unsupervised lay-use for injection of the drug and adequate directions cannot be written for such use; 502(f) (2)—in that the labeling of the device failed to bear adequate warnings against its use for injection of the drug in those pathological

conditions where such use may be dangerous to health, and against unsafe methods of application of the device for injection of the drug; and 502(j)—in that the device was dangerous to health when used with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, the labeling of the device contained directions which provided for its use in an unsterile condition and in a manner resulting in the injection of air into the bloodstream of the body, and the device was dangerous to health when used in accordance with such directions and with the frequency and duration prescribed, recommended, and suggested in its labeling.

The complaint alleged further that the defendants violated the law by shipping, in interstate commerce, the drug which was adulterated and misbranded in the manner specified above, and the device which was misbranded in the manner specified above, and by causing the drug to be accompanied by the above labeling while held for sale after shipment in interstate commerce, which act resulted in the drug being misbranded within the meaning of 502(a) as specified above.

The complaint alleged further that the defendants claimed that the drug was identical in composition to the drug known by the names of "*Koch Treatment*" and "*Glyoxylyde*" which was distributed by Koch Laboratories, Inc., of Detroit, Mich., and which had been adjudged worthless for the treatment of cancer and other serious diseases; that an order to cease and desist (Federal Trade Commission Docket No. 4772) was issued on August 24, 1951 by the Federal Trade Commission against William F. Koch and Louis G. Koch, individuals who served as officers of Koch Laboratories, Inc., prior to its dissolution, ordering the individuals to cease and desist any representations that "*Glyoxylyde*" was an adequate treatment for cancer and other serious diseases, including tuberculosis, epilepsy, and insanity, or that "*Glyoxylyde*" had therapeutic value, or that the use of "*Glyoxylyde*" would be of benefit in the treatment of any disease in the human body or in animals; and that such order was subsequently affirmed by the United States Court of Appeals for the Sixth Circuit on July 8, 1953 (206 F. 2d 311).

DISPOSITION: On 12-30-60, the court issued a temporary restraining order. On 1-4-61, a consent decree of preliminary injunction was filed enjoining the defendants against the acts complained of. On 5-18-61, a petition for an order to show cause in criminal contempt against Thomas Troupe Gammage Reynolds was filed, in the Eastern District of Texas, and he was ordered to show cause why he should not be punished for criminal contempt of the preliminary injunction, arising out of disobedience of the preliminary injunction by the shipment of a number of ampules of the drug, designated by the names "*Koch Treatment*," "*Glyoxylyde*," and "*Koch's Glyoxylyde*," from Palestine, Tex., to Prairie Village, Kans., on 1-15-61; from Tyler, Tex., to Prairie Village, Kans., on 5-4-61; and by the shipment of a device consisting of a hypodermic syringe and needle from Palestine, Tex., to Prairie Village, Kans., on 1-15-61. The shipments were violative in a manner similar to that charged above. On 6-5-61, both the criminal contempt proceedings against Thomas Troupe Gammage Reynolds and the civil action for a permanent injunction against Reynolds, his wife, and his mother, came on for trial by the court. Thomas Troupe Gammage Reynolds pleaded guilty to the charge of criminal contempt and was fined \$500 and sentenced to 6 months' imprisonment, which fine and imprisonment were suspended, and he was placed on 2 years' probation under the special condition that he comply with the terms

of the injunction. (Subsequently, on 12-6-61, the defendant was sentenced to 2 months' imprisonment for violation of the terms of probation.)

On 6-5-61, a consent decree of permanent injunction was entered which permanently enjoined the defendants from doing the following acts:

(a) Introducing and causing to be introduced and delivering and causing to be delivered for introduction into interstate commerce, the drug designated by the names of "*Koch Treatment*," "*Glyoxylyde*," and "*Koch's Glyoxylyde*," or any similar drug which (i) was accompanied by the following written, printed, or graphic matter, or accompanied by any written, printed, or graphic matter substantially to the same effect: the mimeographed leaflets entitled "*The Reynolds Clinic * * * Since 1941*," "*Koch's Glyoxylyde 12X*," "*The Koch Treatment (Glyoxylyde) * * * 3. Arthritis*," "*The Koch Treatment (Glyoxylyde) * * * 2. Bursitis*," "*The Koch Treatment (Glyoxylyde) * * * 1. Alcoholic Neuritis*," "*Order Form*" and "*Glyoxylyde 12X Sterile * * * O=C=C=O*"; a four-page mimeographed brochure entitled "*Glyoxylyde Case Reports*"; and a four-page mimeographed brochure entitled "*The Koch Treatment Patients Diet*"; (ii) bore or was accompanied by any written, printed, or graphic matter which stated, represented, suggested, or implied that such drug contained *Glyoxylyde* and that such drug was adequate and effective in the treatment and prevention of cancer and other diseases and conditions in man, or which was otherwise false and misleading; (iii) bore or was accompanied by labeling containing inadequate directions for the use of such drug in the treatment and prevention of cancer and other diseases and conditions in man; (iv) bore or was accompanied by labeling containing directions for the unsupervised lay-use of such drug for injection; (v) failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, an accurate statement of the quantity of contents, and the common or usual name of such drug; (vi) failed to bear or be accompanied by labeling stating all of the diseases, conditions, and purposes for which such drug was intended and for which it was represented by any means to the public; (vii) failed to bear or be accompanied by labeling containing adequate warnings against the use of such drug for injection in those pathological conditions where its use may be dangerous to health and against unsafe methods of administration by injection of the drug; or (viii) was dangerous to health because such drug is prescribed, recommended, or suggested in its labeling for unsupervised lay-use for injection;

(b) Doing acts with respect to the drug designated by the names "*Koch Treatment*," "*Glyoxylyde*," and "*Koch's Glyoxylyde*," or any similar drug, which caused such drug, while held for sale after shipment in interstate commerce, to bear or be accompanied by labeling which (i) stated, represented, suggested, or implied that such drug contained *Glyoxylyde* and that such drug was adequate and effective in the treatment and prevention of cancer and other diseases and conditions in man, or which was otherwise false and misleading; or (ii) failed to state all of the diseases, conditions, and purposes for which such drug was intended and for which it was represented by any means to the public;

(c) Introducing and causing to be introduced and delivering and causing to be delivered for introduction into interstate commerce, a device which consisted of a hypodermic syringe and needle and which (i) bore or was accompanied by labeling containing directions for the unsupervised lay-use of such device for the injection of the drug designated by the names of "*Koch Treatment*," "*Glyoxylyde*," or "*Koch's Glyoxylyde*," or for the injection of any similar drug; (ii) failed to bear or be accompanied by labeling containing

adequate warnings against use of such device for the injection of the drug designated by the names of "*Koch Treatment*," "*Glyoxylide*," or "*Koch's Glyoxylide*," or for the injection of any similar drug, in those pathological conditions where such use may be dangerous to health and against unsafe methods of application of such device for injection of any such drug; or (iii) was dangerous to health because such device was prescribed, recommended, or suggested in its labeling for use in an unsterile condition and in a manner resulting in the injection of air into the bloodstream of the body.

Thereafter, on 11-15-62, the Government petitioned for another order to show cause in criminal contempt, alleging that Thomas Troupe Gammage Reynolds had violated the permanent injunction by shipping "*Glyoxylide*" from Palestine, Tex., to Minneapolis, Minn., on 10-12-62; from Elsa, Tex., to Minneapolis, Minn., on 10-12-62; from Elsa, Tex., to Kansas City, Kans., on 10-12-62; and from Elsa, Tex., to Cleveland, Ga., on 11-6-62.

Thomas Troupe Gammage Reynolds pleaded not guilty to the charge of violating the permanent injunction. The case was tried before the court on 6-3-63 and 6-4-63. On 6-4-63, he was found guilty and sentenced to 2 years' imprisonment, which was suspended, and placed on 4 years' probation.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

7542. Various prescription drugs. (F.D.C. No. 47910. S. Nos. 77-861/70 T.)
QUANTITY: 4 ctns. of various drugs at Brighton, Mass., in possession of Terrace Pharmacy Co., Inc.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Professional Sample," "Physicians Sample," "Samples Not To Be Sold," "Clinical Trial Supply" and "Physicians Evaluation Package."

RESULTS OF INVESTIGATION: Some of the articles were prescription drugs which had been repacked by the dealer, Terrace Pharmacy Co., Inc., into containers to which were affixed labels bearing such brand names for the drugs as were indicative of their manufacture outside the State of Massachusetts, sample legends, and the names and addresses of manufacturers, packers, or distributors located outside the State of Massachusetts; some of the articles were prescription drugs which had not yet been repacked by the dealer which were in containers to which were affixed labels bearing brand names indicative of their manufacture outside the State of Massachusetts, sample legends, and the names and addresses of manufacturers, packers, or distributors located outside the State of Massachusetts.

LIBELED: 7-27-62, Dist. Mass.

CHARGE: 502(a)—while held for sale, the words "Professional Sample," "Physicians Sample," "Sample Not To Be Sold," "Clinical Trial Supply," "Physician's Sample—Not To Be Sold," "Physician's Evaluation Package" and similar wording on the labels of a number of the articles were false and misleading as applied to such articles in the possession of a repacker and intended for sale and not then intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b) (1)—some of the articles failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(e) (2)—some of the drugs were not designated solely by a name recognized in an official compendium and their labels failed to bear the common or usual name of each

active ingredient; 502(f)(1)—the labeling of some of the articles failed to bear adequate directions for use and the articles were not exempt from that requirement since they were drugs subject to the provisions of 503(b)(1) and their label failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the package of the drug as required by regulations; 503(b)(4)—some of the drugs were subject to 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; 505(a)—the drugs labeled as "Triurate," "Marsilid," and "Dornwal," were new drugs which may not be introduced or delivered for introduction into interstate commerce since applications filed pursuant to 505(b) were not effective with respect to such drugs.

DISPOSITION: 9-10-62. Default—destruction.

7543. Various prescription drugs. (F.D.C. No. 48068. S. Nos. 87-741/60 T.)

QUANTITY: 35,719 tablets and capsules of prescription drugs at Jacksonville, Fla., in possession of McPherson Drug Co.

SHIPPED: On unknown dates, by various drug handlers.

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked by the dealer into bottles having labels bearing brand names indicative of manufacture outside the State of Florida and bearing on some packages the word "Physician's Trial Package," or similar wording, and the names and addresses of manufacturers, packers, or distributors located outside the State of Florida; and quantities of prescription drugs which were not yet repacked and which bore labels bearing brand names indicative of manufacture outside the State of Florida, the words "Professional Complimentary Package," or similar wording, and the names and addresses of manufacturers, packers or distributors located outside the State of Florida.

LIBELED: 8-29-62, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the words "Physician's Trial Package," "Professional Complimentary Package," and similar wording on the labels of a number of the articles were false and misleading as applied to the articles in the possession of a repacker and intended for sale and not intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)(1)—a number of the articles failed to bear a label containing the names and places of business of the manufacturers, packers, or distributors; 502(d)—a number of the articles contained derivatives of the hypnotic substance, barbituric acid, which have been designated by regulations as habit-forming, and their labels failed to bear the name and quantity or proportion of such derivatives and in juxtaposition therewith, the statement "Warning—May be habit forming"; 502(e)(1)—the labels of a number of the articles failed to bear the common or usual name of the articles; 502(e)(2)—a number of the articles were fabricated from two or more ingredients and their labels failed to bear the common or usual name of each active ingredient; 502(f)(1)—the labeling of a number of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were subject to 503(b)(1) and their labels failed to bear an identifying lot or control number as required by regulations; 502(f)(1)—the labeling of a number of the articles failed to bear adequate directions for use since their labeling failed to state the expiration date beyond which the articles should not be used; 502(1)—a number of the articles purported to be drugs composed in whole or in part of penicillin, streptomycin, chlortetra-

cycline, chloramphenicol, bacitracin, or derivatives thereof, and they were not from batches with respect to which certificates were in effect since the drugs had had their original labeling altered or removed in whole or in part; 503(b)(4)—a number of the articles were subject to 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and 505(a)—the articles labeled in part "Capsules Mer/29," "Monase," "Flexin," and "Flexilon," were new drugs which may not be introduced into interstate commerce, since an application filed pursuant to law was not effective with respect to such drugs.

DISPOSITION: 11-19-62. Default—destruction.

7544. Various injectable drugs. (F.D.C. No. 48961. S. Nos. 62-301/3 V.)

QUANTITY: 7 ctns., each containing 10 ampules of a liquid product and 10 ampules of a solid product labeled *Extrait Embryonnaire*; 78 ctns., each containing 14 ampules of *Labcatal*; and 3 ctns., each containing 5 ampules of each of the following products: *Neynormin Dilutionen Nr. 65*, *Neygeront Dilutionen Nr. 64*, *Revitorgan Dilutionen Nr. 26*, and *Revitorgan Dilutionen Nr. 36*, at Indio, Calif.

SHIPPED: Between 12-12-62 and 3-7-63, from Lyon, France, by Institut Merieux; from Geneva, Switzerland, by International Centre for Biological Research; and by an unknown shipper.

LABEL IN PART: (Ctn.) "Extrait Embryonnaire * * * 10 Ampoules D'Extrait Lyophilise Avec Solvant Institut Merieux," (ampule liquid) "Institut Merieux Solvant Special," (ampule solid) "Institut Merieux Extrait Embryonnaire Vole Intramusculaire," (ctn.) "Labcatal J. Gueret Pharmacien-Gerant Panpharma Ag. Bern 14 P.C.A. 23.702 9 Rue R. Salengro Montrouge (Seine) Alesia 84-80 * * * Traitement," and "Neynormin Dilutionen Nr. 65 [or "Neygeront Dilutionen Nr. 64" or "Revitorgan Dilutionen Nr. 26" or "Revitorgan Dilutionen Nr. 36"] Vitorgan GambH-Stuttgart Pharmaz. Preparete."

ACCOMPANYING LABELING: Leaflets entitled "Extrait Embryonnaire" and "Revitorgan Dilutionen * * * Indikationen."

LIBELED: 5-16-63, S. Dist. Calif.

CHARGE: 505(a)—the articles were new drugs which may not be introduced into interstate commerce, since an approval of an application filed pursuant to the law was not effective with respect to such drugs.

DISPOSITION: 7-8-63. Default—destruction.

7545. Atoxin. (F.D.C. No. 49047. S. No. 66-212 V.)

QUANTITY: 141 individually ctn'd. vials at Hato Rey, P.R.

SHIPPED: 3-1-63, from Hialeah, Fla., by Delta Pharmaceuticals, Inc.

LABEL IN PART: (Vial) "Atoxin A Selected Detoxicant Principle Isolated From Liver * * * Each cc. represents the Lipotropic Activity derived from 30 gms. of fresh liver * * * Delta Pharmaceuticals, Inc., Miami, Florida * * * Dosage and administration * * * Intramuscularly."

LIBELED: 7-23-63, Dist. P.R.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drug.

DISPOSITION: 10-16-63. Default—destruction.

7546. Timed disintegration tablets and capsules. (F.D.C. No. 47733. S. Nos. 44-524/5 T, 44-527/8 T.)

QUANTITY: 4 metal cans, containing 2,000 yellow and blue capsules, 12,500 tablets, 2,500 black and red capsules, and 3,500 pink capsules, respectively, at Philadelphia, Pa., in possession of Cabot Pharmaceuticals, Inc.

SHIPPED: 2-9-62 and 4-23-62, from Hoboken, N.J., by Kingston Laboratories, Ltd.

LABEL IN PART: (Can of yellow and blue capsules) "Each Capsule Contains: D-Amphetamine Sulfate 15 mg. Amphetamine Sulfate 15 mg. Thyroid 3 grs. Phenobarbital $\frac{3}{8}$ gr."; (can of tablets) "Each tablet contains D-Amphetamine Sulfate 15 mg. Racemic-Amphetamine Sulfate 15 mg. Thyroid 3 grs. Phenobarbital $\frac{3}{8}$ gr."; (can of pink capsules and can of black and red capsules) "Black & Red Capsules [or "Pink Capsules"] Each Capsule Contains: D.L. Amphetamine Sulfate 30 mg. Thyroid 3 gr. Atropine Sulfate $\frac{1}{180}$ gr. Aloin $\frac{1}{4}$ gr. Phenobarbital $\frac{1}{4}$ gr."

RESULTS OF INVESTIGATION: Analysis showed that the articles released more than half of the amphetamines present in each of them within one hour, and that the yellow and blue capsules and the tablets contained approximately 86 percent and 89 percent, respectively, of the declared amounts of amphetamines and approximately 76 percent and 81 percent, respectively, of the declared amounts of phenobarbital. The pink capsules had been repacked into bottles by the dealer after receipt in cartons from the shipper. The yellow and blue capsules and the tablets had been shipped in bulk drums labeled in part "Kingston Laboratories, Ltd., * * * Hoboken, N.J.," and had been repacked by the dealer into bottles. The black and red capsules had not been repacked by the dealer at the time of sampling. After the articles had been sampled by a Food and Drug Administration inspector, the dealer had placed them in the cans, identifying each article as to its composition and shipper. At the time of sampling, the 4 articles were labeled: (btls. of yellow and blue capsules) "Cabot Dexathen Timecaps": (btls. of tablets) "Cabot Dexathen Time-tabs"; (shipping ctn. of black and red capsules) "Wil-O-Bex 30 Time Disintegration Capsule"; and (btls. of pink capsules) "Pink Cabot Dextron Timesets."

LIBELED: 7-25-62, E. Dist. Pa.

CHARGE: 501(c)—when shipped and while held for sale, the quality of the articles fell below that which each was represented to possess, in that they failed to disintegrate as indicated on their labels; and in that the strength of the 2,000-capsule lot and the tablets differed from that which they purported to possess since such articles contained less than the declared amounts of phenobarbital and amphetamines; 502(a)—the label statements, (2,000-capsule lot) "Each capsule prepared in a special base to allow for the disintegration of the contents throughout a 10 hour period," (12,500-tablet lot) "Part #1 Immediate Release," "Part #2 to dissolve in approximately 4 hours," and "Part #3 to dissolve in approximately 8 hours," and (2,500- and 3,500-capsule lots) "prepared in a special base to allow for the disintegration of the contents throughout a 6-10 hour period," were false and misleading as applied to the articles which did not release the drugs at a uniform rate over the stated periods of time; 502(a)—the label statements, (2,000-capsule lot) "D-Amphetamine Sulfate 15 mg.," "Amphetamine Sulfate 15 mg.," and "Phenobarbital $\frac{3}{8}$ gr.," and (12,500-tablet lot) "D-Amphetamine Sulfate 15 mg.," "Racemic-Amphetamine Sulfate 15 mg.," and "Phenobarbital $\frac{3}{8}$

gr.," were false and misleading as applied to the articles (2,000-capsule lot and 12,500-tablet lot) which contained less than the declared amounts of those ingredients; and 505(a)—the articles were new drugs which may not be introduced or delivered for introduction into interstate commerce, under the provisions of 505(a) since an application filed pursuant to 505(b) was not effective with respect to such drugs.

DISPOSITION: 11-14-62. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE FOR WHICH NONE HAD BEEN ISSUED

DRUGS FOR HUMAN USE*

7547. Diamicina and Neurobasal capsules. (F.D.C. No. 48603. S. Nos. 39-932/3 V, 39-935 V.)

QUANTITY: 1,000 ctnd. btls., and 9 cases, 36 ctnd. btls. each, of *Diamicina* and 10 cases, 48 btls. each, of *Neurobasal capsules*, at Hatlo Rey, P.R., in possession of the dealer, Rogatol Pharmaceutical Co., Inc.

SHIPPED: The *Diamicina* was manufactured by the dealer in part from dihydrostreptomycin sulfate crystalline and neomycin sulfate USP which was shipped in bulk, on 6-11-62 and 8-8-62, from New York, N.Y.; and the *Neurobasal capsules* were shipped in bulk, on 4-12-61, from Baltimore, Md., and repacked by the dealer into bottles.

LABEL IN PART: (Btls. of *Diamicina*) "90 cc. *Diamicina* Cada Cucharada (15 cc.) continene: Sulfato de Neomicina * * * 100 Mg. (1.53 gr.) Dihidro Estreptomicina * * * 150 Mg. (2.3 gr.) * * * Rogatol Pharmaceutical Co., Inc. Hato Rey, Puerto Rico * * *"; (ctns. for btls. in 9-case lot) "90 cc. *Diamicina* * * * Cada 100 cc. continene: Neomicina Sulfato 0.350 Gm. (peso de la base) Dihidroestreptomicina Sulfato 1,000 Gm. (peso de la base) * * * Rogatol Pharmaceutical Co., Inc., Hato Rey, P.R. * * *"; (btls. of *Neurobasal*) "* * * 120 Capsules *Neurobasal* Each six capsules contain: Glutamic Acid (as Monosodium Glutamate) 3.0 Gm. Thiamine Hydrochloride (vit. B₁) 18.0 mg. Aminoacids 240.0 mg. (Leucine, Isoleucine, Lysine, Valine, Methionine, Phenylalanine, Histidine, Tryptophan, Cystine, Arginine, Threonine) Peptones 180.0 mg. Magnesium Phosphate (tri-basic) 180.0 mg. Recommended daily dose: 6 capsules or as directed by physician. Rogatol Pharmaceutical Co., Inc. Hato Rey, P.R. U.S.A. 620507."

ACCOMPANYING LABELING: Leaflets in Spanish language entitled "*Neurobasal*" and extra repack labels for *Neurobasal*.

RESULTS OF INVESTIGATION: Analysis showed that the article, *Diamicina*, (both lots) contained essentially the declared amount of dihydrostreptomycin and (1,000-bottle lot) approximately 60.6 percent and (9-case lot) approximately 53.4 percent, of the declared amount of neomycin base as stated on the bottle labels.

The article, *Neurobasal capsules*, had not been analyzed. It was assumed to contain the ingredients listed on its label.

LIBELED: 1-29-63, Dist. P.R.

CHARGE: *Diamicina*, 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; 502(a)—the label on the

*See also No. 7543.

bottles in the 1,000-bottle lot and the 9-case lot bore the statement "Sulfato de Neomicina * * * 100 mg. (1.53 gr.)" which statement was false and misleading as applied to an article containing less than the declared amount of neomycin; 502(a)—the labeling of the 9-case lot, namely, the bottle label "Sulfato de Neomicina * * * 100 mg. (1.53 gr.)" and carton label "Neomicina Sulfate 0.350 Gm." was false and misleading as applied to an article containing less than the amounts of neomycin declared on the bottle and carton labels, which declared amounts did not agree; 502(1)—the article (all lots) purported to be and was represented as a drug composed in part of a kind of streptomycin and it was not from a batch with respect to which a certificate or release had been issued.

Neurobasal capsules, 502(a)—the accompanying leaflet contained false and misleading representations that the article was adequate and effective for the treatment or prevention of insufficiencies of cerebral function, loss of memory, lack of initiative, less capacity for attention, mental retardation, mental debility, and disorders of psychological origin of sexual functions; 502(f) (1)—in that its labeling failed to bear adequate directions for use, since adequate directions for use cannot be written for the conditions for which it was intended.

DISPOSITION: 8-12-63. Default—destruction.

7548. Streptomycin sulfate and penicillin. (F.D.C. No. 48606. S. Nos. 39-936/7 V.)

QUANTITY: 333 cases, each containing 25 5-gm. vials, and 3 cases, each containing 500 5-gm. vials, of *streptomycin sulfate*; and 2 drums, containing a total of approximately 47 1-billion unit plastic bags, and 32 cases, each containing 100 vials of *penicillin*, at Hato Rey, P.R., in possession of Laboratorios Terrier, Inc.

SHIPPED: 8-11-62 and 11-7-62, from New York, N.Y., by Chas. Pfizer & Co., Inc.

LABEL IN PART: (Vial) "Streptomycin Sulfate Equivalent to 5 Gms. Streptomycin Base * * * Exp. Date Sep 67 * * * Labs. Terrier, Inc. Hato Rey," (drum) "Pfizer Penicillin G Procaine Crystalline with Buffered Penicillin G Potassium Crystalline For Aqueous Injection 100,000 Units of Penicillin G Potassium added to each 300,000 Units of Penicillin G Procaine Units 25,000,000,000 * * * Date of Manufacture * * * Chas. Pfizer & Co., Inc., * * * New York," and (vial) "Bu-Penil 400,000 Units Contains 300,000 units of Crystalline Procaine Penicillin G, and 100,000 Units of Buffered Crystalline Penicillin G Potassium * * * Expires June 1967 Produce[d] for and packed [by] Labs. Terrier, Inc. Hato Rey."

RESULTS OF INVESTIGATION: The articles were shipped in bulk, as described above, to Pfizer Corp., Hato Rey, P.R., and delivered to the dealer. The dealer repacked the articles into vials, as described above.

Analysis showed that the potency of each article was essentially as declared on the labels.

LIBELED: 1-30-63, Dist. P.R.

CHARGE: 502(1)—when shipped and while held for sale, the articles were composed in whole or in part of a kind of penicillin or streptomycin and they were not from batches with respect to which certificates or releases issued pursuant to law were effective.

DISPOSITION: The articles were claimed by the dealer, who failed either to contest or to consent to an entry of a decree of condemnation. A default decree of destruction was subsequently entered on 10-11-63.

DRUGS FOR VETERINARY USE

7549. *Antivi'Sol-S* and *Antivi'Sol-P*. (F.D.C. No. 48447. S. Nos. 28-861/2 V.)

QUANTITY: 21 cases, 6 cans each, of *Antivi'Sol-S*, and 19 cases, 6 cans each, of *Antivi'Sol-P*, at Sheldon, Iowa.

SHIPPED: 8-17-61, from Omaha, Nebr.

LABEL IN PART: (Can) "NBC *Antivi'Sol-S* [or "*Antivi'Sol-P*"] Antibiotics & Vitamins Water Soluble for Swine [or "for Poultry"] Guaranteed Analysis: Dihydrostreptomycin base (as sulfate) 3 grams per pound. Procaine Penicillin 1,000,000 units or 1 gram per pound (Equivalent to 0.6 gm. Crystalline Penicillin G, Master Standard) * * * Northern Biochemical Corp. Sheldon, Iowa * * * Net Weight 3½ Pounds * * * Exp. Date Nov. 30 '61 * * *." (Also "Lot No. 020611" (21 cases) and "Lot No. 350611" (19 cases)).

RESULTS OF INVESTIGATION: Analyses showed that the articles contained (both lots) approximately 99 percent of the declared dihydrostreptomycin potency and approximately 29 percent (21 cases) and 35 percent (19 cases) of the declared penicillin potency.

LIBELED: 1-2-63, N. Dist. Iowa.

CHARGE: 501(c)—while held for sale, the strength of the articles differed from that which they purported to possess; 502(a)—the label statements "Guaranteed Analysis: * * * Procaine Penicillin 1,000,000 units or 1 gram per pound (Equivalent to 0.6 gm. Crystalline Penicillin G, Master Standard)" were false and misleading as applied to products containing less than the declared potency of penicillin; 502(a)—the articles were not adequate and effective as a treatment for the conditions named in the labeling when used as directed; and 502(1)—the articles purported to be and were represented as drugs composed in part of a kind of penicillin and a kind of streptomycin (with added vitamins), and they were not from batches with respect to which a certificate or release had been issued pursuant to 507, and they were not exempt from that requirement, as provided by the exemption regulations, since the articles (both lots) contained added vitamins and they were intended solely for veterinary use and each gram contained less than 2,200 units of penicillin and since the expiration date of the articles had passed; and since the labeling of the article, *Antivi'Sol-P*, contained statements and representations for use in conditions which are not named in the exemption regulations.

DISPOSITION: 2-5-63. Default—destruction.

7550. *Arvicin*. (F.D.C. No. 48395. S. No. 27-761 V.)

QUANTITY: 7 cases, 8 jars each, at Charles City, Iowa, in possession of Dr. Mayfield Laboratories, Inc.

SHIPPED: The article was manufactured by Dr. Mayfield Laboratories, Inc., from penicillin G potassium shipped from Teterboro, N.J., on 3-28-62, dihydrostreptomycin sulfate shipped from New York, N.Y., on 3-28-62, and sodium arsaniolate shipped from North Chicago, Ill., on an unknown date.

LABEL IN PART: (Jar) "Dr. Mayfield *Arvicin* Net Weight ½ Pound * * * Active Ingredients: Each Pound Contains: * * * Streptomycin 3,603 mg. Penicillin 11,000,000 units * * * Manufactured by Dr. Mayfield Laboratories Charles City, Iowa * * * Directions * * * Caution * * * 60922."

RESULTS OF INVESTIGATION: Analysis shows that the article contained less than the declared potency of penicillin and streptomycin.

LIBELED: 12-4-62, N. Dist. Iowa.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; 502(a)—the label statements “Streptomycin 3,603 mg.” and “Penicillin 11,000,000 units” were false and misleading; and 502(1)—the article purported to be a drug composed in part of a kind of penicillin and streptomycin and it was not from a batch with respect to which a certificate or release had been issued.

DISPOSITION: 2-7-63. Default—destruction.

7551. Medicated feed. (F.D.C. No. 48471. S. No. 55-981 V.)

QUANTITY: 80 50-lb. bags at Sioux Falls, S. Dak.

SHIPPED: 11-5-62, from Cherokee, Iowa, by Walnut Grove Products Co., Inc.

LABEL IN PART: (Tag) “Walnut Grove 4x4 Beef Supplement (A) Medicated An aid in the prevention of foot rot caused by Spherophorus Necrophorus Active Drug Ingredient Ethylene Diamine Dihydriodide .011% * * * Chlortetracycline Hydrochloride .070 GM./Lb. * * * Ingredients: * * * Warning: * * * Manufactured by Walnut Grove Products Co., Inc. Atlantic, Iowa.”

LIBELED: 12-3-62, Dist. S. Dak.

CHARGE: 502(1)—when shipped, the article was represented as a drug composed in part of a kind of chlortetracycline, and it was not from a batch with respect to which a certificate or release had been issued.

DISPOSITION: 2-20-63. Consent—claimed by Walnut Grove Products Co., Inc., Atlantic, Iowa, and reprocessed.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

7552. Various prescription drugs. (F.D.C. No. 47091. S. Nos. 24-112 R, 60-993 R, 85-783/4 R, 85-789 R, 25-146 R.)

INFORMATION FILED: 5-31-62, W. Dist. Mo., against Prospect Pharmacy, a partnership, Kansas City, Mo., George Guastello, partner-pharmacist, and Peter Spalitto, employee.

ALLEGED VIOLATIONS: Between 10-20-60 and 6-29-61, the defendants caused *penicillin tablets* (1 count) and *dextro-amphetamine sulfate tablets* (3 counts) to be dispensed once and 3 times, respectively, without a prescription, and caused *phenobarbital tablets* (1 count) to be dispensed once upon a request for a refill of a prescription without authorization by the prescriber, which acts resulted in the articles being misbranded while held for sale after shipment in interstate commerce.

In addition, between 11-5-57 and 7-3-61, while a number of *Entozyme tablets* (1 count) were being held for sale after shipment in interstate commerce, the defendants caused the article to be repacked into a bottle labeled in part “Eskatrol Spansule,” which act resulted in such tablets being misbranded.

CHARGE: *Penicillin tablets* and *dextro-amphetamine sulfate tablets*, 503(b) (1)—while held for sale, the articles were dispensed without a prescription. *Phenobarbital tablets*, 503(b) (1)—while held for sale, the article was dispensed by refilling a prescription without authorization.

Entozyme tablets, 502(a)—the labeling contained false and misleading representations that the article consisted of Eskatrol Spansule capsules; and 502(i) (3)—the article was offered for sale under the name of another drug, namely, Eskatrol Spansule.

PLEA: Partnership and George Guastello—guilty to all counts; Peter Spalitto—guilty to the counts involving *penicillin tablets* and *phenobarbital tablets* and to 1 count involving *dextro-amphetamine sulfate tablets*.

DISPOSITION: 6-22-62. Partnership and George Guastello—\$900 fine each; Peter Spalitto—\$450 fine.

7553. Various prescription drugs. (F.D.C. No. 47319. S. Nos. 30-910 R, 31-993 R, 31-995 R, 31-997/8 R, 32-000 R, 60-121 R.)

INFORMATION FILED: 10-5-62, S. Dist. Miss., against Lawrence Drug Co., a corporation, Laurel, Miss., and Kimsey K. Lawrence, president.

ALLEGED VIOLATIONS: Between 12-29-60 and 1-5-61, the defendants caused *secobarbital sodium capsules* and *Equanil tablets* to each be dispensed twice, and *Hydrodiuril tablets* to be dispensed once, upon requests for prescription refills without authorization from the prescriber, and caused *Metandren Linguets* to be dispensed once without a prescription, which acts resulted in the articles being misbranded while held for sale after shipment in interstate commerce.

In addition, on 10-18-60, while a number of *imitation Miltown tablets* were being held for sale after shipment in interstate commerce, the defendants caused the article to be offered for sale and sold, which act resulted in the article being misbranded.

CHARGE: *Secobarbital sodium capsules*, *Equanil tablets*, and *Hydrodiuril tablets*, 503(b)(1)—while held for sale, the articles were dispensed by refilling prescriptions without authorization.

Metandren Linguets, 503(b)(1)—while held for sale, the article was dispensed without a prescription.

Imitation Miltown tablets, 502(i)(2)—while held for sale, the article was an imitation of another drug; and 502(i)(3)—the article was offered for sale under the name of another drug, namely, Miltown.

PLEA: Nolo contendere.

DISPOSITION: 10-10-62. Corporation—\$250 fine; Lawrence—\$250 fine.

7554. Imitation Serpasil tablets, Serpasil tablets, Diuril tablets, and Seconal Sodium capsules. (F.D.C. No. 47095. S. Nos. 31-322/3 R, 31-372 R, 60-321 R.)

INFORMATION FILED: 5-7-63, W. Dist. La., against Service Drug Store of De Quincy, Inc., a corporation, t/a The Service Rexall Drug Store, De Quincy, La., Douglas M. Norment, secretary-treasurer, and Clyde F. Walker, pharmacist.

ALLEGED VIOLATIONS: On 12-19-60, the corporate defendant caused *imitation Serpasil tablets*, while being held for sale after shipment in interstate commerce, to be dispensed in filling a prescription for Serpasil tablets, and between 1-5-61 and 1-24-61, the defendants caused *Diuril tablets*, *Seconal Sodium capsules*, and *Serpasil tablets* to be dispensed once each, upon requests for a prescription refill without obtaining authorization by the prescriber, which acts resulted in the drugs being misbranded.

CHARGE: *Imitation Serpasil tablets*, 502(i)(2)—while held for sale, the article was an imitation of another drug; and 502(i)(3)—the article was sold under the name of another drug.

Diuril tablets, *Seconal Sodium capsules*, and *Serpasil tablets*, 503(b)(1)—the articles were dispensed upon request for a prescription refill without obtaining authorization by the prescriber.

PLEA: Guilty by the corporation to 4 counts; by Norment to 2 counts; and by Walker to 1 count.

DISPOSITION: 8-6-63. Corporation—\$500 fine; Norment—\$150 fine; Walker—\$100 fine.

7555. Dexedrine Sulfate tablets, dextro-amphetamine sulfate tablets, secobarbital sodium capsules, and imitation Chloromycetin capsules. (F.D.C. No. 48163. S. Nos. 13-315 R, 59-301 R, 59-305 R, 59-321/2 R, 59-324 R, 59-326 R.)

INFORMATION FILED: 5-14-63, N. Dist. Ill., against Windsor Pharmacy, Inc., Chicago, Ill., Marvin D. Cahan, president, Leizer Spector, pharmacist, and Jerome J. Ehrenreich, assistant pharmacist.

ALLEGED VIOLATIONS: Between 1-5-61 and 3-29-61, *secobarbital sodium capsules* were dispensed 3 times, *Dexedrine Sulfate tablets* were dispensed twice, and *dextro-amphetamine sulfate tablets* were dispensed once without a prescription, which acts caused the articles to be misbranded. In addition, on 1-10-61, *imitation Chloromycetin capsules*, represented to be Chloromycetin capsules, were shipped from Chicago, Ill., to Whiting, Ind.

LABEL IN PART: (Btl.) "Windsor Pharmacy M.D. Cahan, R. Ph. * * * Chloromycetin 250 mg. #100."

CHARGE: *Secobarbital sodium capsules*, *Dexedrine Sulfate tablets*, and *dextro-amphetamine sulfate tablets*, 503(b)(1)—while held for sale, the articles were dispensed without a prescription.

Imitation Chloromycetin capsules, 501(d)(2)—when shipped, *imitation Chloromycetin capsules* had been substituted for Chloromycetin capsules.

PLEA: Nolo contendere by Ehrenreich to the count involving *dextro-amphetamine sulfate tablets*, and a count involving *secobarbital sodium capsules*; by Spector to a count involving *Dexedrine Sulfate capsules*, and a count involving *secobarbital sodium capsules*; and by both Windsor Pharmacy, Inc., and Cahan to the other 3 counts.

DISPOSITION: 10-7-63. Windsor Pharmacy, Inc.—\$1,000 fine suspended; Cahan—\$1,000 fine, plus cost, \$700 of which fine was suspended; Ehrenreich—\$1,000 fine of which \$900 was suspended. 11-1-63. Spector—\$100 fine suspended.

7556. Amphetamine phosphate tablets. (F.D.C. No. 47889. S. Nos. 28-408 T, 29-561 T.)

INFORMATION FILED: 11-8-62, Dist. Kans., against J. Louis Ransom, M.D., Topeka, Kans.

ALLEGED VIOLATIONS: On 10-11-61, the defendant caused *amphetamine phosphate tablets* to be dispensed once without a prescription. On 3-2-62, the defendant caused to be introduced into interstate commerce, at Topeka, Kans., for delivery to Kansas City, Mo., *amphetamine phosphate tablets* which were misbranded.

RESULTS OF INVESTIGATION: Investigation showed that there was no bona fide doctor-patient relationship between the defendant and the recipient of the articles.

CHARGE: 502(b)—when shipped, the article failed to bear a label containing (1) the place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents; 502(e) (1)—it failed to bear a label containing the common or usual name of the article; 502(f)—the labeling of the article failed to bear (1) adequate directions for use and (2) adequate warnings against use; 503(b) (4)—the label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and 503(b) (1)—while held for sale, the article was dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 3-8-63. Fine of \$250, plus costs, suspended sentence of 1 year in prison, and probation for 1 year.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

7557. Herb capsules. (F.D.C. No. 48173. S. Nos. 46-981 T, 46-983 T.)

INFORMATION FILED: 2-15-63, E. Dist. Mo., against Dayton L. Lewis, Salem, Mo.

ALLEGED VIOLATIONS: On 5-3-62, the defendant, following his receipt of quantities of herbs, namely, powdered red clover buds, powdered comfrey, powdered blue violets and powdered verbane, which had been shipped in interstate commerce, and his fabrication of such herbs into capsule form and packing such capsules into vials, caused a number of vials of such capsules to be sold for use for the treatment of cancer, which act resulted in such *herb capsules* being misbranded while held for sale.

On 5-24-62, the defendant also caused quantities of *herb capsules* to be introduced into interstate commerce, at Salem, Mo., for delivery to East Alton, Ill.

CHARGE: 502(b)—the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents; 502(e) (2)—the label of the article failed to bear the common or usual name of each active ingredient; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use for the purpose and condition for which it was intended, namely, for the treatment of cancer.

PLEA: Guilty.

DISPOSITION: 3-29-63. Probation for 2 years.

7558. Various prescription and nonprescription drugs. (F.D.C. No. 48119. S. Nos. 5-881 T, 5-884 T, 5-886 T, 5-890 T.)

QUANTITY: 745 btl., 461 cards, and 609 samples, at Washington, D.C., in possession of Chesapeake Drug Store.

SHIPPED: On unknown dates, from various drug handlers.

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked by the dealer into containers having labels bearing brand names indicative of manufacture outside the District of Columbia, and the words (some labels) "Professional Sample" or similar wording; (some labels) "Caution: New Drug Limited by Federal Law to Investigational Use"; and (some labels) the names and addresses of manufacturers, packers, or dis-

*See also Nos. 7541-7543, 7547, 7556.

tributors located outside the District of Columbia; and quantities of prescription drugs which were not yet repacked, and bearing brand names of drugs as were indicative of their manufacture outside the District of Columbia, the words "Caution: New Drug Limited by Federal Law to Investigational Use," and the names and addresses of the manufacturers, packers, or distributors located outside the District of Columbia; and quantities of non-prescription drugs which were repacked by the dealer into containers bearing brand names of drugs as were indicative of their manufacture outside the District of Columbia.

LIBELED: 9-21-62, Dist. Columbia.

CHARGE: 502(a)—while held for sale, the words "Professional Sample" and similar wording on the labels of a number of the articles were false and misleading as applied to the articles in the possession of a repacker and intended for sale and not intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(a)—the words "Caution: New Drug Limited by Federal Law to Investigational Use" on the labels of a number of the articles were false and misleading as applied to those articles then in the possession of a repacker and intended for sale and not then intended for investigational use; 502(b)(1)—a number of the articles failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(e)(2)—a number of the articles were not designated solely by a name recognized in an official compendium and their labels failed to bear the common or usual name of each active ingredient contained therein; 502(f)(1)—the labels of a number of the articles failed to bear adequate directions for use and they were not exempt from such requirement under the regulations since they were not drugs required to be dispensed upon prescription within the meaning of 503(b)(1); 502(f)(1)—the labeling of a number of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were subject to the provisions of 503(b)(1), and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history as required by regulations; and 502(f)(1)—the labels of a number of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were drugs required to be dispensed upon prescription within the meaning of 503(b)(1), and they failed to comply with the conditions for exemption provided by regulations.

DISPOSITION: 10-29-62. Default—26 bottles of new drugs were delivered to the Food and Drug Administration, and the remainder of the drugs were destroyed.

7559. Anterior pituitary tablets. (F.D.C. No. 48103. S. No. 53-691 T.)

QUANTITY: 7,994 unlabeled pkgs., each containing 28 tablets, at Olympia, Wash.

SHIPPED: 7-23-62, from Anaheim, Calif., by Mills Pharmaceuticals, Inc.

LIBELED: 9-21-62, W. Dist. Wash.

CHARGE: 502(b)(1)—when shipped and while held for sale, the article failed to bear a label containing the name and place of business of manufacturer, packer, or distributor; 502(b)(2)—the article failed to bear a label containing an accurate statement of the quantity of contents; 502(e)(1)—the article failed to bear a label containing the common or usual name of the article; and 502(f)(1)—the labeling of the article failed to bear adequate directions for

use since the article was inert and adequate directions for use cannot be written.

DISPOSITION: 10-22-62. Default—destruction.

7560. Pyralgin products. (F.D.C. No. 48596. S. Nos. 17-062/3 V.)

QUANTITY: 3 cases, each containing 100 15-cc. btls. of *Pyralgin liquid*, and 9 cases, each containing 28 24-tablet boxes of *Pyralgin tablets*, at Jeffersonville, Ind.

SHIPPED: Between 10-11-62 and 11-19-62, from Houston, Tex., by Savage Laboratories, Inc.

LABEL IN PART: (Btl.) "No. 914 Pyralgin 15 cc. Each teaspoon (15 cc.) contains Methampyrone Sodium 0.5 gm. * * * Caution: Federal law prohibits * * * Savage Laboratories, Inc., Houston, Texas" and (box) "For Pain For general medical and dental use Adult Dose: 2 Tabs. * * * Methampyrone Sodium (Savage) * * * Savage Laboratories, Inc., Houston, Texas."

ACCOMPANYING LABELING: Booklet entitled "Reprints from February 1961 issue Pediatric Clinics of North America Vol. 8 No. 1"; folder entitled "Pyralgin for pain"; card entitled "Pyralgin Pediatric Suppositories"; Index Card entitled "Pyralgin Antipyretic and Analgesic"; single sheets entitled "Pyralgin Liquid * * * Bibliography Rev. 12/61 Savage," "Wait without anxiety using Pyralgin," and "Fast predictable control of fever."

LIBELED: 1-23-63, S. Dist. Ind.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that there was an enormous amount of clinical evidence supporting the efficacy and limited toxicity of the drug; that the incidence of reaction to *Pyralgin* was extremely low; that there were five dosage forms to meet every need, and dosage may be varied greatly without danger of overdose; that *Pyralgin* was essentially without toxic effect; that repeated dosages might be prescribed if certain conditions were followed; that *Pyralgin* was a distant chemical relation of aminopyrine; that in contrast to aminopyrine no cases of agranulocytosis had been reported with use of this drug; that *Pyralgin* had been found to be one of the best of the antipyretics; that no unfavorable effects were encountered when *Pyralgin* was given in recommended doses as needed; that *Pyralgin* was essentially without toxic effect and the recommended doses might be doubled and tripled in an emergency; that, although there had been more than 10,000,000 doses of *Pyralgin* given, there had never been a report of agranulocytosis resulting from short-term use; that *Pyralgin* was an ideal preoperative and postoperative analgesic; that *Pyralgin* was reported as the most effective antipyretic in hospital use, with no unfavorable side effects encountered; that *Pyralgin* was much less toxic than aspirin; that *Pyralgin* had a very great margin of safety; that *Pyralgin* was the best of all antipyretics; that in speed of effects, in certainty of action, in absence of side effects, *Pyralgin* outranked all antipyretic drugs; that *Pyralgin* was safe and nontoxic; that *Pyralgin* was the best intermediate analgesic available to the profession today; that a wide range of dosage was possible; that *Pyralgin* had an extremely low incidence of reaction; that the article was extremely safe and that there was no significant hazards involved in use of the drug; that the article did not or had not been known to cause agranulocytosis; that it was not a derivative or a close chemical relative to aminopyrine; that dosages might be varied widely; that the article might be used for prolonged periods without any hazard; that

the article was a mental relaxant; and that it was adequate and effective treatment for fear of pain and anxiety; 502(f) (1)—the labeling of the article failed to bear adequate directions for use and it was not exempt from that requirement since the labeling in its entirety failed to bear the information required by regulation, in that the labeling furnished, or purported to furnish, information for use, or prescribed, recommended, or suggested a dosage for use of the drug and it failed to bear adequate information for such use, including indications, effects, dosages, frequency and duration of administration, and relevant hazards, contraindications, side effects, and precautions under which a practitioner licensed by law could administer the drug safely and for the purposes for which it was intended, including all the conditions for which it was represented; and since certain articles of labeling, namely, the Index Card, and single sheets entitled "Wait Without Anxiety," bore information for use of the drug and failed to bear the date of issuance or the date of the latest revision of such articles of labeling as required by regulations; and 502(b) (2)—the labeling of the boxes of *Pyralgin tablets* failed to bear an accurate statement of the quantity of contents.

DISPOSITION: 3-29-63. Default—destruction.

7561. Cough drops. (F.D.C. No. 47211. S. Nos. 26-190/1 T.)

QUANTITY: 101 cnts., each containing 24 pkgs. of 3 boxes each, of *vitamin C cough drops*, and 222 cnts., each containing 24 pkgs. of 3 boxes each, of *medicated cough drops*, at Livonia, Mich.

SHIPPED: Between 11-2-61 and 1-8-62, from Greensboro, N.C., Philadelphia, Pa., and Cleveland, Ohio, by Vick Chemical Co.

LABEL IN PART: (Pkg.) "Vicks Vitamin C Cough Drops 17 Drops New! Lemon Flavor Plus Vitamin 'C' Thrift Pak" and (pkg.) "Vicks Medicated Cough Drops 17 Drops Thrift Pak Famous Vick Regular Flavor * * * Vick Chemical Company, Division of Richardson-Merrell Inc. Greensboro, N.C. New York, N.Y. Philadelphia, Pa."

LIBELED: 3-14-62, E. Dist. Mich.

CHARGE: *Vitamin C cough drops*, 502(a)—when shipped, the label contained false and misleading representations that the article, because of its vitamin C content, was effective in helping to build resistance to colds, coughs, and sore throats; 502(b) (1)—the label (package of 3 boxes) failed to bear the name and place of business of the manufacturer, packer, or distributor; 502(e) (2)—the label (package of 3 boxes) failed to bear the common or usual name of each active ingredient; and 502(f) (2)—the article was offered for use for coughs and sore throat and its label failed to bear a statement warning that in case of severe sore throat or persistent cough or sore throat, or if the condition is accompanied by high fever, headache, nausea, and vomiting, a serious condition may exist and a physician should be consulted, and that the article should not be administered to children under 3 years of age unless directed by a physician.

Medicated cough drops, 502(f) (2)—when shipped, the article was offered for relief of coughs due to colds and the label failed to bear a statement warning that persons with a high fever or persistent cough should not use the article unless directed by a physician.

DISPOSITION: 10-1-62. Default—delivered to a charitable institution.

7562. Hair tonic. (F.D.C. No. 47697. S. Nos. 38-176 T, 38-178 T.)

QUANTITY: 14 1-gal. btls., 95 21-oz. btls., 24 12-oz. btls., and 248 8-oz. btls., at Baton Rouge, La.

SHIPPED: Between 10-29-58 and 4-25-62, from Mobile, Ala., by Sure Shot Laboratories.

LABEL IN PART: (Btl.) "Sure Shot for Loose Dandruff Scales Contains: Resorcinol, Salicylic Acid, Powdered Borax, Tincture Cantharides, Alcohol 50% * * * Mfg. by Sure Shot Laboratories 311 St. Michael St. Mobile, Ala. Directions for excessive oiliness of the hair, the scalp and dandruff * * * For irritated skin, pimples, or burns."

RESULTS OF INVESTIGATION: Examination showed that the article contained a color additive, namely, an uncertifiable blue dye.

LIBELED: 7-9-62, E. Dist. La.

CHARGE: 501(a) (4) (A)—when shipped, the article contained, for purposes of coloring only, a color additive, namely, an uncertifiable blue dye, which was unsafe within the meaning of 706(a); 502(a)—the label contained false and misleading representations that the article was an adequate and effective treatment for irritated skin, pimples, and burns; and 502(f) (2)—the labeling failed to bear warning statements that excessive use of the article may cause temporary discoloration of blond, white, or red hair; that in case of deep wounds or serious burns, a physician should be consulted; that if redness, irritation, swelling, or pain persisted or increased, or if infection occurred, use of the article should be discontinued and a physician consulted.

DISPOSITION: 10-2-62. Default—destruction.

7563. Cosmetic products. (F.D.C. No. 48822. S. Nos. 7-665/9 V.)

QUANTITY: 12 2-oz. btl. of *Sta-Free deodorant-antiperspirant*, 28 4-oz. jars of *cleansing treatment*, 44 4-oz. jars of *night treatment*, 36 2-oz. jars of *hormone oil*, and 70 1½-oz. jars of *complexion make-up*, at Boston, Mass.

SHIPPED: Between 1-7-62 and 10-10-62, from Bridgeport, Conn., by Rilling Dermetics, Inc., Div. of Turner-Hall Corp.

LABEL IN PART: (Btl.) "Sta-Free Deodorant-Anti-perspirant Dermetics Turner-Hall Corp. New York, N.Y. Contains: Aluminum chlorhydroxide complex"; (jar) "Airborn Cleansing Treatment Dermetics * * * Turner-Hall Corp. New York"; (tag) "Dermetics Airborn the only cosmetic that effectively attracts vital oxygen out of the air * * * provides Oxygen-Retention to breathe in nature's unsurpassed beauty ingredient, oxygen * * * complexion is renewed, reborn * * * draws refreshing oxygen under make-up in order to minimize pore clogging * * * exclusive Aerating-Action."; (jar) "Airborn Night Treatment Dermetics * * * Turner-Hall Corp. New York," "Ageless Moisturizing Hormone Oil * * * Contains 7500 I.U. natural estrogens per oz. * * * Turner-Hall Corp., Distr. N.Y.," and "Airborn Complexion Make-Up Dermetics Turner-Hall Corp.—New York, N.Y."

RESULTS OF INVESTIGATION: The name and address of the manufacturer, quantity of contents statement, statement of the active drug ingredient, directions for use, and statement warning that the article was not to be applied to broken skin and if a rash developed use of the article was to be discontinued, were formed in the plastic material of the container for the article, "*Sta-Free deodorant-antiperspirant*," and were inconspicuous due to lack of color contrast with the background.

LIBELED: 3-22-63, Dist. Mass.

CHARGE: *Sta-Free deodorant-antiperspirant*, 502(c)—when shipped, the information required to appear on the label under 502(b) (1) and (2), 502(e) (2), 502(f) (1) and (2), namely, the name and address of the manufacturer,

packer, or distributor, and an accurate statement of the quantity of the contents, the common or usual name of each active ingredient, adequate directions for use as an antiperspirant, and the warning statement that the article was not to be applied to a broken skin and that if a rash developed use of the article was to be discontinued, was not prominently placed on the label with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) as to render it likely to be read by the ordinary individual under customary conditions of purchase and use.

Cleansing treatment, night treatment, and complexion make-up, 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles caused rejuvenation of the skin and cured skin blemishes.

Hormone oil, 502(a)—when shipped, the name "Ageless" and statements in the labeling of the article represented and suggested that the article was effective in preventing the aging processes, retarding the appearance of aging shadows, distressing lines, and wrinkled skin, which statements were false and misleading; and 502(f) (1)—the labeling of the article failed to bear directions limiting application of the article to 20,000 international units of estrone, or an equivalent estrogenic material, in the period of one month.

DISPOSITION: 5-20-63. Default—destruction.

7564. Young Again cosmetic cream. (F.D.C. No. 48617. S. Nos. 31-561 V, 31-582 V.)

QUANTITY: 5 ctns., containing a total of 504 1-oz. btl., at Studio City, Calif., in possession of Jeanean Paris.

SHIPPED: 1-24-63, from Milwaukee, Wis., by Kolmar Laboratories, Inc.

LABEL IN PART: (Btl.) "Young Again * * * Cleanse face thoroughly before retiring, apply sparingly on face where lines appear. Jeanean Paris, distr. 7373 Sunset Blvd. Hollywood 46, Calif." and (ctn.) "Biogenic Stimulator" (handwritten).

ACCOMPANYING LABELING: Booklets entitled "Biogenic Stimulator Report #67 September 10, 1957"; a single page headed "Jeanean Paris," containing before and after pictures; letters to customers on Jeanean Paris letterhead containing reorder forms; 30-day guarantee slips; a newspaper advertisement headed "Look Young Again For the New Year"; and a testimonial letter signed "Roseberry Koestler."

RESULTS OF INVESTIGATION: The booklet entitled "Biogenic Stimulator Report #67 September 10, 1957" was received from the manufacturer and separated by the dealer into two 9-page sections, the second section being entitled "Basis Of The Effect of Tissue Extracts." The before and after pictures were removed by the dealer from the booklet described above and reprinted locally as a single sheet used as a "throwaway." The other items were printed locally by the dealer.

LIBELED: 2-13-63, S. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the label statements "Young Again" and "Apply sparingly on face where lines appear" were false and misleading in their representations that the article was adequate and effective for rejuvenating the face to an appearance of youth and to eradicate facial lines caused by the aging process; 502(a)—the accompanying labeling contained false and misleading representations that the article was adequate and effective for removing facial wrinkles; 502(a)—the labeling,

namely, the carton and accompanying labeling, contained false and misleading representations that a constituent of the article, namely, Biogenic Stimulator, was adequate and effective as a treatment for psoriasis, chronic torpid ulcers, osteoarthritis, corneal ulcers, varicose ulcers, chronic eczema, X-ray dermatitis, lupus vulgaris, arteriosclerosis, endocrine hypofunctioning, amenorrhea, ulcers cruris, decubital ulcers, badly healing skin defects (open fractures, with or without infection, etc.), and many other serious diseases; 502(e) (2)—the article was represented to be a drug by reason of the label statement (ctn.) "Biogenic Stimulator" and it failed to bear a label containing the common or usual name of each active ingredient; and 502(f) (1)—the labeling failed to bear adequate directions for use.

DISPOSITION: 4-9-63. Default—destruction.

7565. Devices designated as "Electronic Magnetic Model G," "Electro Sine Galvanic Model 200," "Radioclast Model 40," "Auto Electronic Radioclast Model 20, Series 800," and "Electronic Analysis Instrument Model F." (Inj. No. 413.)

COMPLAINT FOR INJUNCTION FILED: 4-25-62, N. Dist. Ohio, against the L. L. Roby Manufacturing Corp., Tiffin, Ohio; International Electronics Research Society, Inc., Tiffin, Ohio; Lester L. Roby, president and treasurer of the L. L. Roby Manufacturing Corp., and secretary-treasurer of International Electronics Research Society, Inc.; and Lester L. Roby, Jr., vice president of L. L. Roby Manufacturing Corp.

NATURE OF DEVICES: The *Electronic Magnetic Model G* device consisted of a suitcase-type container which, on opening, displayed a control panel and a storage drawer at the bottom. The control panel contained the necessary controls and power outlets for the operation of the device. There were two magnetic electrodes present, each consisting of a coil of wire encased in a pancake-type housing, one side of which was brass and the other side steel. Two electronic electrodes were also supplied with the device and these consisted of strips of metal with cable attached. The power supply consisted of a power transformer, rectifier, and filter for the purpose of supplying low-voltage alternating current and high-voltage direct current to the rest of the instrument. A 7.2-cycle-per-second phase shift oscillator was present for the purpose of generating and supplying a low-voltage faradic current to the patient. A 220-cycle-per-second phase shift oscillator and amplifier was also present for supplying a 220-cycle-per-second current to the magnetic electrodes.

In the actual operation of the *Electronic Magnetic Model G* device the two electronic electrodes were placed over the liver and spleen, or at the base of the neck, and the magnetic electrodes were placed on each side of the diseased portion of the body. The electronic electrodes applied a 7.2-cycles-per-second electrical current to the body but this current was of no known therapeutic value as applied by this device. The magnetic electrodes produced a weak, varying magnetic field of no known therapeutic value when applied to a patient.

The *Electro Sine Galvanic Model 200* device consisted of a suitcase-type container, with a carrying handle at the top, housing an electronic circuit for the production of various forms of electrical current. The control panel contained a switch, pilot lights, a 0-25 DC ammeter and an array of knobs for the selection and adjustment of the current type, intensity, and frequency. The panel also had three female outlet plugs to which applicators were attached and one plug labeled "foot switch." Two sets of electrodes were also included with the device, as well as cloth pads approximately 1¼ inches across and two metal strips.

When the *Electro Sine Galvanic Model 200 device* was plugged into an electrical outlet it produced surged, pulsating, or continuous faradic pulses and a galvanic current.

When the faradic current produced by this device was applied to a patient, a tetanic-type contraction might occur in the muscle with an intact nerve supply present. In the use of galvanic current a continuous current was passed through the tissues and might produce a prickly sensation.

The *Radioclast Model 40 device* consisted of a desk-type console which contained a large control panel with 24 control knobs, 2 meters, a timer, 6 pilot lights, a push button designated as "food test" and 9 electroterminal jacks. Included at the bottom of the control panel was a metal detector plate, a metal cup, and a glass or bakelite detector plate. The various knobs and dials were used to measure, select, and control the frequencies and intensities. The "food test" portion of the device was alleged to be of use to the operator in selecting an appropriate diet for the patient. When plugged into an electrical outlet, the treatment portion of the device was intended to supply to the patient various electrical frequencies generated by the device. The diagnostic portion of the device purportedly measured various electrical frequencies supposedly emanating from the patient, and, depending upon the readings secured, it was claimed that the presence or absence of diseases or abnormal body conditions might be determined.

The device was intended to detect, identify, and measure various hypothetical frequencies emanating from all the cells in the body, normal cells, diseased cells or pathogenic organisms. In this manner, a diagnosis of the diseased body was allegedly obtained as to the organs involved, pathogenic organism involved, and the intensity of the disease. The patient was then "treated" by passing certain harmonizing or tuned frequencies, determined by the diagnostic or analysis section of the device, back into the body. The basic elements of the electronic circuit by which the above was accomplished were two tuned amplifiers to measure input and a radio frequency oscillator to furnish the treatment output.

The claimed analysis or diagnosis was made by the device amplifying the detected frequencies and applying them to a wire screen under the bakelite detector plate. The operator manipulated the dials with one hand and rubbed the bakelite plate with the fingers of the other hand. Supposedly, when the device was in resonance with a frequency from the body, the operator's fingers became "sticky" on the bakelite plate.

In actual use, this device was not capable of detecting or measuring any characteristic frequencies from the body since such frequencies were non-existent.

For the purpose of selecting an appropriate diet for a patient a "food test plate" was provided connected to the "in" terminal. Since no electrical ground return was associated with the "food test plate," only random capacitative pickup could be associated with this terminal. The device was intended to measure frequencies characteristic of the foods placed on the test plate.

The *Auto Electronic Radioclast Model 20, Series 800 device* consisted of a wood cabinet containing a control panel leading to a combination of electronic circuits. The control panel contained pilot lights, a line switch, a heater switch and a series of three dials alleged to be of use in determining the identity of diseased organs. Three other dials purported to identify the disease conditions present and additional dials were intended to determine the intensity

of the disease conditions. The amount of current passing through the device was controlled by an intensity rheostat. A detector plate, as an attachment, purported to enable the operator of the device to locate the point of maximum reaction and thus determine the location of the disease in the body.

When plugged into an electrical outlet, the *Auto Electronic Radioclast Model 20, Series 800 device* operated in a manner similar to that described for the aforesaid *Radioclast Model 40*. A complete diagnosis of all disease conditions in the body was purportedly made by measurement of hypothetical characteristic electrical vibrations from the body. Then treatment of these conditions was supplied by passing similar characteristic radio frequency currents back into the body but these were of such low intensity as to be totally worthless. Detection of disease and determination of when cure was complete was to be made by the operator by rubbing his fingers on the bakelite detector plate.

The *Electronic Analysis Instrument Model F device* was housed in a wood console cabinet fitted with a control panel containing a direct current milliammeter, two pilot lights, a number of switches and 12 dials. The device did not generate an electrical current, but purported to measure electrical impulses allegedly emanating from diseased tissue and thus diagnosed the presence or absence of disease. It had a detector plate, as an attachment, alleged to be of use to the operator in diagnosing the location and extent of disease in the body.

When plugged into an electrical outlet and connected to a patient, the device was not capable of detecting, identifying, or measuring any quantity, function, or condition of the human body.

CHARGE: The complaint alleged that the defendants were engaged in the business of manufacturing, assembling, repairing, promoting, selling, and causing to be introduced into interstate commerce, the above-described devices which were misbranded as follows:

Electronic Magnetic Model G, 502(a)—the labeling of the device contained false and misleading representations that the device was capable of treating body areas of congestion, inflammation, and irritation, aiding the body to eliminate areas of congestion, inflammation, and irritation, and supplying stimulating energy to the body; and 502(f)(1)—the labeling of the device failed to bear adequate directions for use for the purpose for which it was intended, namely, for the treatment of disease in man, since the device was worthless for the treatment of disease in man and adequate directions could not be given for such use;

Electro Sine Galvanic Model 200, 502(f)(1)—the labeling of the device failed to bear adequate directions for use and it was not exempt from such requirement since it was a prescription device, and it failed to comply with the conditions for exemption prescribed in the regulations;

Radioclast Model 40, 502(f)(1)—the labeling of the device failed to bear adequate directions for use for the purposes for which it was intended, namely, for the diagnosis and treatment of disease in man and for use as a food tester and diet selector, since the device was worthless for use for such purposes and adequate directions could not be given for such use;

Auto Electronic Radioclast Model 20, Series 800, 502(f)(1)—the labeling of the device failed to bear adequate directions for use for the purposes for which it was intended, namely, for the diagnosis and treatment of disease in man, since the device was worthless for use for such purposes and adequate directions could not be given for such use;

Electronic Analysis Instrument Model F, 502(f) (1)—the labeling of the device failed to bear adequate directions for use for the purpose for which it was intended, namely, for the diagnosis of disease in man, since the device was worthless for use for such purpose and adequate directions could not be given for such use.

The complaint alleged further that the defendants had been warned on various occasions that the devices were misbranded; that such warnings had been given in various libel actions against a number of the devices; and that despite such warnings, the defendants continued to cause the introduction and delivery for introduction into interstate commerce, of misbranded devices.

DISPOSITION: The defendant, L. L. Roby Manufacturing Corp., filed a motion to strike from the complaint the allegations describing the devices and the libel actions against a number of the devices. The other defendants also filed a motion to dismiss the injunction action against them on the ground that the complaint failed to state a claim against them upon which release could be granted. On 9-6-62, the court overruled the defendants' motions. On 5-27-63, the defendants having consented, the court entered a decree of permanent injunction enjoining the defendants from directly or indirectly doing the following acts:

(A) Introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, and more particularly, from delivering or causing to be delivered to customers and other persons living outside the State of Ohio for transportation in interstate commerce, the devices, whether new, used, or repaired, designated as "*Electronic Magnetic Model G*," "*Radioclast Model 40*," or "*Auto-Electronic Radioclast Model 20, Series 800*," or "*Electronic Analysis Instrument Model F*," or any of their components, parts or accessories, or the same devices by any other designation, or any similar devices, which:

- (1) are accompanied by written, printed, or graphic matter which contains statements that the devices are adequate and effective for the diagnosis, cure, mitigation, treatment, or prevention of any disease or other abnormal condition in the body of man, or that the devices are adequate and effective for use as a food tester and diet selector, or which are otherwise misbranded within the meaning of 21 U.S.C. 352(a); or
- (2) which fail to bear in their labeling a statement of each and every condition and purpose for which such devices are intended to be used, together with sufficient information to enable the user to use the device for each such condition and purpose, or which are otherwise misbranded within the meaning of 21 U.S.C. 352(f) (1);

PROVIDED, however, that the defendants may ship any of said devices to any qualified researcher for the purpose of engaging in bona fide research, provided that the following conditions are first met:

- (a) That defendants furnish to the Food and Drug Administration a statement signed by the researcher to whom the device is to be shipped, setting forth:
 - (1) the scientific training and experience of the researcher;
 - (2) the facilities available to the researcher for the conduct of such research;
 - (3) a protocol of the research to be conducted;

- (4) that the device will be used solely by him or under his direct supervision for investigation and research.
- (b) That defendants shall not ship any device to any such researcher until the Food and Drug Administration has given written approval of the researcher and the protocol after examination of the material submitted in accordance with (a).
 - (c) That the defendants and any firm or organization with which any of them are associated will receive no payment, directly or indirectly, for any such device or for the use of it by such researcher.
 - (d) That the device shall not be used upon any patient without the patient's express knowledge that the device is being used upon him for research purposes and the patient's consent to such use.
 - (e) That the use of the device shall not be substituted for, or serve as a reason for, delaying the diagnosis or treatment of any patient by any other method which good medical judgment would dictate for the care of the patient.
 - (f) Every three months, the researcher shall furnish to the defendants, with a copy to the Device Branch, Division of Medical Review, Food and Drug Administration, Washington, D.C., a complete case report on each patient upon whom the device is used, including medical history, physical examination, all laboratory findings, an exact description of objective findings by other diagnostic methods, an exact description of diagnostic findings by the use of the device, and the results, if any, of any treatment administered to patient by use of the device and, if applicable, the necessity for other treatment of any nature.

(B) Introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, and more particularly, from delivering or causing to be delivered to customers and other persons living outside the State of Ohio for transportation in interstate commerce, the device, whether new, used, or repaired, designated as "*Electro Sine Galvanic Model 200*," including its components, parts, and accessories, or the same device by any other designation, or any similar device, unless and until:

- (a) the device is sold to, or on the prescription or other order of, a practitioner licensed by law to use or order the use of the device;
- (b) the label of the device bears
 - (1) The statement "Caution: Federal law restricts this device to sale by or on the order of a _____," the blank to be filled with the descriptive designation of a practitioner licensed by the law of the state in which he practices to use or order the use of the device; and
 - (2) The method of its application or use.
- (c) the package from which the device is to be dispensed bears or contains labeling containing complete information for the use of the device, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented;

- (d) all labeling that furnishes or purports to furnish information for use of the device, contains adequate information for the use of the device, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented; and
- (e) all labeling, except labels and cartons, bearing information for use of the device also bears the date of the issuance or the date of the latest revision of such labeling.

7566. Neurolinometer devices and Research Model devices (4 seizure actions).

F.D.C. No. 47690. S. Nos. 33-289 T; 33-290 T; 34-287 T; 62-799 T.)

QUANTITY: 2 *Neurolinometer devices*, at Forest Lake, Minn., and 3 *Research Model devices*, at Anoka, Duluth, and Fairmont, Minn.

SHIPPED: On various dates, from Toftness Chiropractic Clinic, and Foundation For The Advancement of Chiropractic Research, Inc., Cumberland, Wis.

LABELS IN PART: "Neurolinometer Toftness System Cumberland, Wisconsin" and "Research Model * * * Limitation of Use: This instrument has no known therapeutic, diagnostic, or analytical value and shall not be used for any such purpose. Its use is strictly limited to personal research work by duly qualified practitioners in Chiropractic."

RESULTS OF INVESTIGATION: The *Neurolinometer* was a device housed in a black, suitcase-type container, about 15 inches long, 9 $\frac{3}{4}$ inches wide, and 5 $\frac{1}{2}$ inches deep. The face of the device contained 8 knobs variously labeled in part "ten," "one," "cervical," or "base." The device otherwise consisted of a monopolar electrode, a single-stage amplifier, and a power supply unit, the output of which was applied to a section of wire mesh attached beneath a sheet of bakelite.

The *Research Model* was a device housed in a grey-colored box, one end of which was a storage well containing a white powder used to dry the surface of the bakelite detector plate in the upper right-hand corner of the box. The control panel contained two plugs for electrode outlets, a switch, fuse, and a variable dial graduated from 0 to 100. One electrode was a small metal disc attached to a wooden handle and the other electrode was a plastic-enclosed metal coil mounted on a metal gooseneck-type support.

LIBELED: 6-27-62 and 6-28-62, Dist. Minn.

CHARGE: 502(a)—when shipped and while held for sale, the *Research Model devices* bore statements which were false and misleading as applied to a product which was intended for use in the diagnosis of disease in the course of the professional practice of practitioners in chiropractic; 502(b) (1)—the labels of the *Research Model devices* failed to bear the name and place of business of the manufacturer, packer, or distributor; and 502(f) (1)—the labeling of all the devices failed to bear adequate directions for use for the purpose for which they were intended, namely, for the diagnosis of disease in man, in that the articles were worthless for use for such purpose and adequate directions could not be given for the use of the articles for such purpose.

DISPOSITION: 10-26-62. Default—delivered to the Food and Drug Administration.

7567. Micro-Dynamometer devices (7 seizure actions). (F.D.C. Nos. 47818, 47940, 48215, 48219, 48321, 48353, 48413. S. Nos. 37-280 T; 20-859 T; 77-911 T; 96-125 T; 38-401 V; 36-409 V; 53-536 V.)

QUANTITY: 7 devices, at Ponchatoula, La., Amarillo, Tex., Enfield, Conn., Borger, Tex., Kosciusko, Miss., De Ridder, La., and Portland, Oreg.

SHIPPED: Between 1-1-54 and 9-27-62, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "For Scientific Body Analysis The Ellis Micro-Dynamometer Mfd. by Ellis Research Laboratories, Inc., Chicago U.S.A."

ACCOMPANYING LABELING: Various pieces of literature pertaining to the device.

RESULTS OF INVESTIGATION: Examination indicated that the devices were essentially galvanometers for measuring electrical currents and electrical potentials of small magnitude. Each device was mounted in a metal cabinet, on the face of which was a scale or meter intended to measure the flow of current in milliamperes, together with a number of dials which could be set at numbered or lettered positions. The dial settings were intended to increase or decrease the resistance to the current flowing through the device. The current which flowed and was measured by the scale or meter was generated by closing the circuit between two dissimilar metal "probes." The circuit was closed by placing the "probes" at different points on the human body, by placing the "probes" together, or by immersing them in water.

LIBELED: 8-10-62, E. Dist. La.; 9-6-62, N. Dist. Tex.; on or about 10-18-62, Dist. Conn.; 11-21-62, N. Dist. Tex.; 11-7-62, N. Dist. Miss.; 11-21-62, W. Dist. La.; 12-18-62, Dist. Oreg.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for diagnosing disease; and 502(f) (1)—the labeling of the articles failed to bear adequate directions for use and they were not entitled to any exemption from that requirement.

DISPOSITION: 1-10-63; 12-17-62; 12-14-62; 2-12-63; 4-15-63; 3-11-63; 2-6-63. Default—6 devises destroyed; 1 device delivered to the Food and Drug Administration.

7568. Micro-Dynamometer devices (24 seizure actions). (F.D.C. Nos. 47726, 47825/6, 47902, 47904, 47916, 47930, 47957, 48011, 48018, 48294, 48304, 48309. S. Nos. 69-823/5 T; 50-333/6 T, 50-339 T; 15-793 T, 16-446 T, 58-293/4 T, 72-129/30 T, 72-689/90 T, 72-693/7 T; 22-317 T; 55-370 T, 77-165/8 T, 77-644/5 T; 76-463 T; 40-542 T, 41-461 T, 74-242 T; 64-348 T, 64-350 T; 47-289 T, 47-291 T, 67-868 T; 73-149/52 T; 37-873 T, 60-283/4 T; 36-328 T, 36-330/1 T, 37-299 T, 38-260 T, 59-807 T; 95-721 T, 95-527/30 T, 10-526/7 V.)

QUANTITY: 58 devices, at Warwood and Wheeling, W. Va.; San Jose and Santa Cruz, Calif.; Henderson, Fulton, Lone Oak, Greenville, Louisville, Elizabethtown, and Vine Grove, Ky.; Roy, Utah; Jacksonville, Orlando, Winter Park, Ocala, Nokomis, and Fort Myers, Fla.; Denver, Colo.; New York, Kingston, and Bronx, N.Y.; West Columbia and Barnwell, S.C.; Paragould, Little Rock, and Jonesboro, Ark.; Rochester, N.Y.; Booneville, Aberdeen, and Amory, Miss.; Hartselle, Jasper, Huntsville, Gadsden, Tuscaloosa, and Decatur, Ala.; and Buffalo, Kenmore, Hamburg, Cheektowaga, Horseheads, Jamestown, and Dunkirk, N.Y.

SHIPPED: On various dates, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "For Scientific Body Analysis The Ellis Micro-Dynameter Mfd. by Ellis Research Laboratories, Inc., Chicago, U.S.A."

ACCOMPANYING LABELING: Literature pertaining to the device.

LIBELED: 7-17-62, N. Dist. W. Va.; 8-15-62, N. Dist. Calif.; 8-31-62, 9-1-62, 9-6-62, W. Dist. Ky.; 7-27-62, Dist. Utah; on or about 7-24-62, M. Dist. Fla.; 8-9-62, Dist. Colo.; 8-10-62, S. Dist. N.Y.; 8-15-62, E. Dist. S.C.; 9-12-62, 9-13-62, E. Dist. Ark.; 9-10-62, W. Dist. N.Y.; 11-5-62, N. Dist. Miss.; 10-9-62, N. Dist. Ala.; and 10-17-62, W. Dist. N.Y.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for diagnosing diseases; and 502(f) (1)—the labeling of the articles failed to bear adequate directions for use, and the articles were not entitled to any exemptions from that requirement.

DISPOSITION: 8-21-62; 2-20-63; 1-11-63, 12-31-62, 12-11-62; 3-4-63; 2-6-63; 12-3-62; 10-26-62; 9-14-62; 1-8-63; 10-29-62; 4-15-63; 11-9-62; 11-27-62. Default—44 devices destroyed; 14 devices delivered to the Food and Drug Administration.

DRUG ACTIONABLE BECAUSE OF INSANITARY CONDITIONS

7569. Caffeine timed disintegration capsules. (F.D.C. No. 48249. S. No. 64-924 T.)

QUANTITY: 2 drums, one containing 6,000 capsules and one containing 500 capsules, and 73 ctns., 12 12-capsule btls. each, at Saugus, Calif.

SHIPPED: Between 3-15-62 and 3-21-62, from Philadelphia, Pa., by Philadelphia Laboratories, Inc.

LABEL IN PART: (Drum) "Caffeine TDC Each capsule contains Caffeine 100 mg. Dose * * * Control #36241 Philadelphia Labs., Inc., Philadelphia 23, Pa." and (btl.) 12 Timed-disintegration Wide-Awake capsules * * * Each capsule contains approximately 100 mgm. of Caffeine in a special base that provides for timed disintegration of the contents throughout a period of 6-10 hours. * * * 143362 Distributors Windsor Corporation * * * Los Angeles, Calif."

RESULTS OF INVESTIGATION: The article was shipped in bulk drums and thereafter repacked into bottles by the dealer at Saugus, Calif. Analysis showed that the article contained the pesticide chemicals, DDT and lindane.

LIBELED: 10-24-62, S. Dist. Calif.

CHARGE: 501(a) (2)—when shipped, the article had been prepared and packed in bulk drums under insanitary conditions whereby it may have been rendered injurious to health.

DISPOSITION: 12-21-62. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICES FOR HUMAN USE*

7570. Imitation Dexedrine Sulfate tablets and imitation Dexamyl tablets. (F.D.C. No. 46697. S. Nos. 72-609/10 R.)

*See also Nos. 7541, 7546, 7547, 7555.

INFORMATION FILED: 6-22-62, S. Dist. Calif., against Charles G. King, t/a Regent Pharmacy, Santa Monica, Calif.

ALLEGED VIOLATIONS: On 3-8-61, while a number of orange, heart-shaped, biconvex, single-scored tablets containing dextro-amphetamine sulfate and a number of green, heart-shaped, biconvex, single-scored tablets containing dextro-amphetamine sulfate and amobarbital were being held for sale after shipment in interstate commerce, the defendant caused the articles to be re-packed into bottles labeled in part: "DEXEDRINE Sulfate * * * S.K.F. TABLETS * * * SMITH, KLINE & FRENCH LABORATORIES" and "DEXAMYL * * * Smith Kline & French Laboratories, Philadelphia," respectively, which acts resulted in the dextro-amphetamine sulfate tablets being misbranded and the dextro-amphetamine sulfate and amobarbital tablets being adulterated.

CHARGE: 502(a)—the statement "DEXEDRINE SULFATE TABLETS" appearing on the label of the bottle of dextro-amphetamine sulfate tablets was false and misleading in that it represented that the article consisted of Dexedrine Sulfate tablets manufactured by Smith, Kline & French Laboratories, Inc., whereas it consisted of *imitation Dexedrine Sulfate tablets*; 502(i) (2)—the dextro-amphetamine sulfate tablets were an imitation of another drug, namely, Dexedrine Sulfate; and 501(d) (2)—in the case of the dextro-amphetamine sulfate and amobarbital tablets, *imitation Dexamyl tablets* had been substituted for Dexamyl tablets.

PLEA: Guilty.

DISPOSITION: 12-17-62. \$1,000 fine.

7571. Stemutrolin Lyophilized. (F.D.C. No. 49068. S. No. 47-098 V.)

QUANTITY: 1,573 ctns., each containing 2 10-cc. vials, at Decatur, Ill., in possession of Lincoln Laboratories, Inc.

SHIPPED: 11-2-62, from Hicksville, N.Y.

LABEL IN PART: (Vial) "Sterile Multiple Dose Vial * * * Stemutrolin Lyophilized. After reconstitution with diluent each cc. contains 500 I.U. Chorionic Gonadotropin. * * * For Intramuscular Injection * * * Caution * * * Lincoln Laboratories, Inc., Decatur, Illinois" and "Sterile Diluent * * * Stemutrolin Each cc. of Diluent contains * * * Lincoln Laboratories, Inc., Decatur, Illinois."

ACCOMPANYING LABELING: Carton insert entitled "Stemutrolin Lyophilized Chorionic Gonadotropin Composition * * * Indications and Uses: * * * Lincoln Laboratories, Inc. Decatur, Illinois."

RESULTS OF INVESTIGATION: The article was manufactured by the dealer in part from chorionic gonadotropin powder shipped in interstate commerce, as described above. Assay showed that the article had a chorionic gonadotropin potency of less than 25 percent of the labeled claim.

LIBELED: 6-24-63, S. Dist. Ill.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "After reconstitution with diluent each cc. contains 500 I.U. Chorionic Gonadotropin," was false and misleading.

DISPOSITION: 9-16-63. Consent—destruction.

7572. Aspirin, phenacetin, and belladonna compound capsules. (F.D.C. No. 49253. S. No. 71-135 V.)

QUANTITY: 2 drums, containing a total of approximately 65,000 capsules, at Lansing, Mich.

SHIPPED: 2-21-62, from Bryan, Ohio.

LABEL IN PART: (Drum) "Each capsule contains: Aspirin $2\frac{1}{2}$ gr. Phenacetin 2 gr. Po. Ext. Belladonna Leaves $\frac{1}{12}$ gr."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 86 percent of the declared amount of aspirin and that the aspirin was decomposing.

CHARGE: 501(c)—while held for sale, the strength of the article differed from, and its quality fell below, that which it was purported to possess; and 502(a)—the label statement "Each capsule contains: Aspirin $2\frac{1}{2}$ gr." was false and misleading as applied to a product containing less than the declared amount of aspirin.

DISPOSITION: 11-12-63. Default—destruction.

7573. Iodophthalein sodium. (F.D.C. No. 49196. S. No. 39-321 X.)

QUANTITY: 20 cases, each containing 120 100-gm. btls., at New York, N.Y.

SHIPPED: Prior to 1-11-63, from outside the State of New York.

RESULTS OF INVESTIGATION: Analysis showed that the article failed to conform to the requirements of National Formulary XI in that it contained less than 85 percent of tetraiodophenolphthalein.

LIBELED: 7-26-63, S. Dist. N.Y.

CHARGE: 501(b)—while held for sale, the article purported to be and was represented as a drug, *iodophthalein sodium*, the name of which was recognized in an official compendium, The National Formulary XI, and its strength differed from the standard set forth in such compendium; and 502(a)—the label statement "100 Grams Iodophthalein Sodium U.S.P. XII" was false and misleading as applied to a product containing less than the declared amount of this ingredient.

DISPOSITION: 9-11-63. Default—destruction.

7574. Rubber prophylactics (4 seizure actions). (F.D.C. Nos. 48344, 48352, 48367, 48384. S. Nos. 46-113 V; 46-328/9 V; 12-414/5 V; 12-412/13 V.)

QUANTITY: 250 boxes, each containing 72 2-unit pkgs., at Carlinville, Ill.; 300 ctns., each containing 72 2-unit pkgs., and 100 ctns., each containing 48 3-unit pkgs., at Hot Springs, Ark.; 18 ctns., each containing 72 2-unit pkgs., and 139 ctns., each containing 72 2-unit pkgs., at Huntley, Ill.; 100 ctns., each containing 72 2-unit pkgs., and 50 ctns., each containing 72 2-unit pkgs., at Chicago, Ill.

SHIPPED: 10-1-62; 10-2-62; and 10-4-62; from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Spartans Prophylactics Package of Two M & M Rubber Co., K.C. 8, Mo. * * * Sold For The Prevention of Disease Only"; "Big Chief Transparent Prophylactics Package of Two [or "Package of Three"] Sold For The Prevention of Disease Only * * * H. L. Blake Co., Inc. * * * Hot Springs, Arkansas"; "Concord Prophylactics Package of Two Sold for The Prevention of Disease Only * * * Distributed by M & M Rubber Co., Kansas City, Mo."; "WC Prophylactics Package of Two Sold For the Pre-

vention of Disease Only * * * Distributed by White's Comb Vendor Incorporated * * * Elgin, Illinois"; "Royal Marquis Prophylactics Package of Two Distributed by Royal Products Co. Chicago, Illinois Sold For The Prevention of Disease Only"; and "Tops Prophylactics * * * M & M Rubber Co. Kansas City 8, Mo."

RESULTS OF INVESTIGATION: Examination showed that the articles were defective in that a number of prophylactics in each lot contained holes.

LIBELED: 10-29-62, S. Dist. Ill.; 11-5-62, W. Dist. Ark.; 11-15-62, N. Dist. Ill.; and 11-26-62, N. Dist. Ill.

CHARGE: 501(c)—when shipped, the quality of the articles fell below that which they purported to possess; and 502(a)—the label statement, "Prophylactics," of some articles and the label statement, "Sold For The Prevention of Disease Only," of some articles, was false and misleading as applied to an article containing holes.

DISPOSITION: 11-29-62; 12-3-62; and 12-21-62. Default—destruction.

7575. Rubber prophylactics. (F.D.C. No. 48354. S. No. 15-514 V.)

QUANTITY: 12 ctns., each containing 72 boxes of 2 prophylactics each, at New Albany, Ind.

SHIPPED: 10-8-62, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Box) "Duke Prophylactics Package of Two Sold For The Prevention of Disease Only Lion Latex Corp. Dallas, Texas."

RESULTS OF INVESTIGATION: Examination of 163 prophylactics showed that 1.8 percent were defective in that they contained holes.

LIBELED: On or about 11-15-62, S. Dist. Ind.

CHARGE: 501(c)—when shipped, the quality of the article differed from that which it was purported to possess; and 502(a)—the label statement "Sold For The Prevention of Disease Only" was false and misleading as applied to a product containing holes.

DISPOSITION: 12-27-62. Default—destruction.

7576. Rubber prophylactics. (F.D.C. No. 48277. S. No. 3-143 V.)

QUANTITY: 48 ctns., each containing 48 vials of 3 prophylactics each, at Oak Hill, W. Va.

SHIPPED: 10-15-62, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Vial) "Swan * * * Prophylactics Sold For The Prevention of Disease Only M & M Rubber Co. Kansas City 8, Mo. Package of Three."

RESULTS OF INVESTIGATION: Examination of 288 prophylactics showed that 2.4 percent were defective in that they contained holes.

LIBELED: On or about 11-8-62, S. Dist. W. Va.

CHARGE: 501(c)—when shipped, the quality of the article differed from that which it was purported to possess; and 502(a)—the label statement "Sold For The Prevention of Disease Disease Only" was false and misleading as applied to a product containing holes.

DISPOSITION: 11-29-62. Default—destruction.

7577. Rubber prophylactics. (F.D.C. No. 48448. S. No. 27-566 V.)

QUANTITY: 188 ctns., 12 pkgs. each, at Omaha, Nebr.

SHIPPED: 8-27-62 and 9-5-62, from North Kansas City, Mo., by Dean Rubber Manufacturing Co.

LABEL IN PART: (Pkg.) "Peacocks Reservoir Ends No. 18 one dozen rolled * * * Dean Rubber Manufacturing Co., North Kansas City, Mo." and (unit) "Peacocks Dean Rubber Mfg. Co."

RESULTS OF INVESTIGATION: Examination of 188 prophylactics showed that 2.5 percent were defective in that they contained holes.

LIBELED: 11-19-62, Dist. Nebr.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "An aid in Preventing Venereal Diseases" was false and misleading as applied to a product containing holes.

DISPOSITION: 12-28-62. Default—destruction.

DRUGS FOR VETERINARY USE*

7578. Turkey grower, medicated. (F.D.C. No. 49292. S. No. 10-554 X.)

QUANTITY: 29 100-lb. bags at Irwin, Pa.

SHIPPED: 7-15-63, from Buffalo, N.Y., by Allied Mills, Inc.

LABEL IN PART: (Tag) "Wayne Universal Turkey Grower Medicated M-53 for aiding in the prevention of outbreaks of Histomoniasis (Blackhead) and Hexamitiasis in turkeys when fed as directed on this label. Active Drug ingredient: Nithiazide * * * 0.03 percent * * * Allied Mills, Inc. Chicago, Illinois pellets."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 63.33 percent of the declared amount of Nithiazide.

LIBELED: 8-29-63, W. Dist. Pa.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Active Drug ingredient: Nithiazide * * * 0.03 percent * * *" was false and misleading.

DISPOSITION: 9-19-63. Default—destruction.

7579. Kassik's hog pellets. (F.D.C. No. 48985. S. No. 54-288 V.)

QUANTITY: 18 80-lb. bags at Milligan, Nebr., in possession of Kassik Companies.

SHIPPED: The article was manufactured in part from ingredients shipped on 8-10-62 and 1-7-63, from Charles City, Iowa, and Indianapolis, Ind.

LABEL IN PART: (Bag) "Kassik's Micro Engineered 14% Complete Hog Pellets Medicated For Swine Only * * * Active Drug Ingredients: Hygromycin B 0.006 grams (6000 units) per lb. 3-Nitro-4-Hydroxyphenylarsonic Acid 0.0025% * * * Manufactured by Kassik Companies Milligan, Nebraska."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately .013 percent of 3-nitro-4-hydroxyphenylarsonic acid.

LIBELED: 5-27-63, Dist. Nebr.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "3-Nitro-4-Hydroxyphenylarsonic Acid 0.0025%" was false and misleading.

*See also Nos. 7549, 7550.

The libel alleged also that the article was adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 7-16-63. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS AND DEVICES FOR HUMAN USE*

7580. Carrot, celery root, and beet juices. (F.D.C. No. 48182. S. Nos. 55-784/6 R.)

INFORMATION FILED: 1-31-63, W. Dist. Wash., against Dorwin B. Cook, t/a Cook's Finer Food, Seattle, Wash.

ALLEGED VIOLATIONS: While quantities of the articles were being held for sale after shipment in interstate commerce, the defendant caused the articles to be held for sale for use for various diseases, conditions, and purposes for which the article was not adequate and effective, while accompanied by various labeling relative to the articles, which act resulted in the articles being misbranded.

LABEL IN PART: (Btl.) "Biotta Lacto-Carrot [or "Celery" or "-Beet"] Pure Carrot [or "Celery Root" or "Beet"] Juice U.S.A. Importer Dorwin Cook * * * Seattle 7, Wash., Net Contents 1 pt. 3 fl. ozs."

ACCOMPANYING LABELING: Leaflet entitled "Here's to you . . . Biotta Juices" and reprint entitled "The Benefits Obtainable from Using Lacto-Fermented Vegetable Juices."

CHARGE: *Carrot juice*, 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the treatment and prevention of fatigue, obstipation, chronic disturbances of gastrointestinal tract, unspecific dermatoses, nervous and overstrained conditions, obesity, cardiac conditions, and cancer.

Celery root juice, 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the treatment and prevention of fatigue, obstipation, chronic disturbances of the gastrointestinal tract, unspecific dermatoses, nervous and overstrained conditions, obesity, rheumatism, cardiac conditions, and cancer.

Beet juice, 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the treatment and prevention of fatigue, obstipation, chronic disturbances of the gastrointestinal tract, unspecific dermatoses, nervous and overstrained conditions, obesity, liver and gallbladder conditions, anemia, improper blood pressure, cardiac conditions, and cancer.

PLEA: Nolo contendere.

DISPOSITION: 6-3-63. \$300 fine.

7581. Slim-Mint chewing gum. (F.D.C. No. 43137. S. No. 51-316 P.)

QUANTITY: 4 cases, each containing 144 40-tablet boxes, and 30 cases, each containing 144 20-tablet boxes, at the dealer's warehouse, Chicago, Ill.; and 100 cases, each containing 144 20-tablet (or 40-tablet) boxes at the various dealer's retail stores serviced by the dealer's warehouse.

*See also Nos. 7541-7543, 7546, 7547, 7552, 7558, 7560-7566, 7568, 7570-7577.

SHIPPED: Between 5-1-57 and 5-31-59, from New York, N.Y., by Thompson Medical Co., Inc.

LABEL IN PART: (Box) "Tablets * * * Slim-Mint Chewing Gum * * * Exclusive Distributors Thompson Medical Co., Inc., N.Y. 10, N.Y. * * * INGREDIENTS Active Ingredients: Benzocaine, Methylcellulose, Oil of Anise, Dextrose, Oil of Peppermint, Oil of Wintergreen, Oil of Cinnamon, Oil of Clove. Also contains natural Kelp (Fucus). Each tablet contains 0.02 mgm. of Iodine."

ACCOMPANYING LABELING: Display carton reading in part "Reduce-Lose 5-10-20 Pounds Fast Without Special Dieting"; display card reading in part "Now! Take off Pounds & Inches REDUCE"; box insert reading in part "Important Directions * * * How to Lose Unsightly Weight The Healthy Happy Slim-Mint Way"; tear sheet and newspaper mat reading in part "Eat What You Want - Yet Lose Up to 3-5-9 Pounds a Week"; tear sheet reading in part "Eat What You Want - Yet Lose Pounds and Inches Fast"; streamer reading in part "Reduce Without Dieting"; and placards reading "Life! Now! Lose Up To 5 Pounds a Week - Reduce."

RESULTS OF INVESTIGATION: The accompanying labeling had been either printed locally or furnished to the dealer on behalf of the shipper of the article.

LIBELED: 5-1-59, N. Dist. Ill.; amended libel 11-20-59.

CHARGE: 502(a)—when shipped and while held for sale, the name of the article, "*Slim-Mint chewing gum*," and its accompanying labeling contained false and misleading representations that the article was an adequate and effective treatment for obesity.

DISPOSITION: On 5-22-59, Thompson Medical Co., Inc., claimed the article. Thereafter, the claimant filed a notice of a motion to strike those portions of the libel of information, warrant of seizure and receipt which refer to *Slim-Mint chewing gum* in the possession of the various dealer retail stores serviced by the dealer warehouse, on the grounds that portions of the libel, warrant, and receipt were impertinent, irrelevant, and incompetent in that (a) the United States marshal did not at any time enter any one of the dealer's retail stores for the purpose of effecting a seizure of articles in the possession of such stores, and (b) any seizure of articles in the possession of various dealer retail stores in numerous states purportedly affected by the seizure of the articles in the possession of the dealer warehouse, constituted a multiple seizure prohibited by Section 304(a) of the Federal Food, Drug, and Cosmetic Act.

On 11-20-59, the libel was amended to substitute the shipping dates mentioned above and to allege that portions of the article which had been shipped during that period remained in the possession of the dealer's Chicago warehouse and the dealer's retail stores.

On 2-16-60, the claimant's motion to strike was overruled and an order was entered granting leave to the claimant to file an answer to the libel within 30 days.

On 3-17-60, Thompson Medical Co., Inc., filed an answer which denied that the Government's libel of information was filed in accordance with the law, and denied that it was a "libel" of a "certain article of drugs"; claimant alleged that it was multiple libels of, for the most part, uncertain articles of drug.

By way of affirmative defense, the claimant stated in part:

A. That no articles of drug in any of the dealer's retail stores had been arrested and taken into custody or seized as required by law.

B. That many of the dealer's retail stores serviced by the dealer's warehouse were not within the jurisdiction of the court and accordingly the portions of the libel referring to the dealer's various retail stores serviced by the dealer's warehouse were not within the jurisdiction of the court.

C. That only the article of drug seized at the warehouse constituted "a certain article of drug" and that seizure of any other article of drug at a separate location constituted a separate seizure.

D. That uncertain quantities of articles of drug in unidentified stores could not be libeled.

E. That the court had no *in rem* jurisdiction over uncertain quantities of articles of drug in unidentified stores.

F. That no representation had been made for the product, "*Slim-Mint chewing gum*," claiming that it was directly in and of itself an adequate and effective treatment for obesity but that the product was an aid to appetite control which by assisting in curbing the intake of excess calories attacked the basic cause of overweight.

G. That the newspaper mat, tear sheets, streamers and placards referred to in the libel did not accompany the article seized.

H. That the newspaper mat and tear sheets were not labels or labeling, but constituted advertising.

I. The product, "*Slim-Mint chewing gum*," was not misbranded when shipped or while held for sale.

On 4-4-60, the Government served written interrogatories on the claimant and thereafter the claimant served written interrogatories on the Government. Subsequently, the interrogatories were answered.

On 12-12-60, the case came on for trial before court and jury. On 12-22-60, the jury rendered a verdict in favor of the claimant and the court dismissed the libel and ordered the release of the goods.

On 1-3-61, the Government moved for a new trial and moved to stay the execution of the judgment; the court denied the motion for a new trial but granted a stay of execution. On 3-1-61, the Government filed a notice of an appeal to the United States Court of Appeals for the Seventh Circuit. Thereafter, the United States Court of Appeals for the Seventh Circuit heard the Government's appeal and, on 3-2-62, rendered the following opinion (300 F. 2d 144):

KNOX, *Circuit Judge*: "The government brought this action *in rem* under the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A. § 334, to condemn Slim-Mint Chewing Gum allegedly misbranded in violation of the Act, 21 U.S.C.A. § 352(a), which provides that a drug shall be deemed misbranded:

"If its labeling is false or misleading in any particular.

The libel of information refers to:

[T]he following described articles of written, printed and graphic matter which accompany said article of drug as labeling and which contain statements relating thereto, namely:

A newspaper mat reading 'Eat What You Want-Yet Lose Up to 3-5-9 Pounds a Week';

An unknown number of tear sheets reading 'Eat What You Want-Yet Lose Up to 3-5-9 Pounds a Week!' and 'Eat What You Want-Yet Lose Pounds and Inches Fast';

An unknown number of streamers entitled 'Reduce Without Dieting' (in red ink); and

An unknown number of placards reading 'Life! Now! Lose Up To 5 Pounds a Week-Reduce * * *.'

and charges:

3. That the aforesaid article (all lots) was misbranded when introduced into, while in, and while held for sale after shipment in interstate commerce, within the meaning of said Act, 21 U.S.C. 352(a) in that the name 'Slim-Mint Chewing Gum' and statements and designs appearing in its labeling, namely, the display carton and card, the box label and insert, the newspaper mat and tear sheet reading 'Eat What You Want-Yet Lose Up to 3-5-9 Pounds a Week!', the tear sheet reading 'Eat What You Want-Yet Lose Pounds and Inches Fast', the streamers entitled 'Reduce Without Dieting' (in red ink), and the placards reading 'Life! Now! Lose Up to 5 Pounds a Week * * Reduce * * *', accompanying said article, contains statements and designs which represent and suggest that the article is an adequate and effective treatment for obesity, which statements are false and misleading since the article is not an adequate and effective treatment for obesity.

"A claim to the attached cases of Slim-Mint was filed by Thompson Medical Company as bona fide owner.

"There was no contention that the Slim-Mint article was adulterated or harmful to health.

"The jury heard evidence of medical witnesses called by the government and by the claimant, and lay witnesses who testified for claimant. There was no motion for a directed verdict. The jury returned a verdict for claimant. The Trial Court denied the government's motion for new trial. This appeal followed.

"The government contends that the record shows that the labeling is false and the article clearly misbranded. The Trial Court instructed the jury:

You must find the Slim-Mint Gum to be misbranded, therefore, if you find that any one of the statements made in the labeling is false or misleading.

The government asserts that the jury failed to follow this instruction. The government also poses the theory that it is not precluded from seeking review of the adequacy of the evidence, even though it first raised the question in its motion for a new trial.

"The government relies on *United States v. Harrell*, 8 Cir., 1943, 133 F. 2d 504. That case involved eminent domain proceedings. The Eighth Circuit held (at page 506) that:

Since the government failed to move the trial court, at the close of the evidence, for a directed verdict on the ground that the evidence was insufficient to sustain a verdict for the appellees, and since the government took no other equivalent action, it is not entitled as of right to a review of the question of the sufficiency of the evidence to support the judgment. [citations omitted]

However, the Eighth Circuit in *Harrell* also held that where the public interest is directly and substantially involved, a federal appellate court, in order to prevent a manifest miscarriage of justice, may notice an apparent error not properly raised on the record. The Court stressed the fact (at page 507) that:

[T]he rule is invoked only in the exceptional case, and its application in any particular case may not be accepted as a departure from the general rules governing the preservation of questions for review here.

"In *Harrell*, the Eighth Circuit found an obvious error in the Trial Court's charge to the jury (at page 505) :

I am going to say to the jury the Government has taken these leases and whatever you believe the market value is from all the evidence and the circumstances in this case, you are entitled to that damage.

"The Eighth Circuit found nothing in the record to support the charge that the government had taken the leases in question, or to excuse the failure of counsel for the government to accept that charge without objection, and concluded that the government's acceptance must lie in something which occurred in chambers prior to the trial, and which was not brought into the record. The Eighth Circuit then went on to say that no evidence was presented to the jury from which the fair value of the leases could be determined. The leases had never been introduced in evidence. No witness before the jury had professed any knowledge of their terms or conditions. The jury was left in ignorance of the rent, how long the leases ran, whether the lessees were required to drill for oil on penalty of forfeiture, whether the leases were renewable, etc.

"The government cites a number of cases in which *Harrell* has been cited with approval. In *Lambur v. Yates*, 8 Cir., 1945, 148 F. 2d 137, plaintiff, a tenant, sought to recover excessive rentals collected in violation of the Emergency Price Control Act. The case was pleaded and tried, without objection, on the theory that there were twelve separate violations. The contention that there had been only one violation (over a period of 12 months) was raised in the appellate court for the first time. However (1) numerous cases involving the same statute were pending, (2) no federal appellate court had construed the statute, and (3) the decisions of state and district courts were in conflict. Therefore, the Eighth Circuit ruled on this issue [adversely to appellant] despite the delay in raising the question.

"In *Hoblik v. United States*, 8 Cir., 1945, 151 F. 2d 971, another eminent domain case, the Court restated the rule (at page 972) that :

The question of the sufficiency of the evidence to sustain a verdict is usually not subject to review on appeal unless the record shows that, during the trial, that question was presented to the trial court by a motion for a directed verdict, a request for a ruling or an instruction, or some other equivalent action. [citation omitted]

but then added :

In this case, however, we shall assume that the question of the sufficiency of the evidence to support the verdict is properly before us. In a case such as this, where the sole issue was one of fact for the jury, it reasonably can be urged that a verdict, if entirely without evidentiary support, should be set aside to prevent manifest miscarriage of justice. [citing *Harrell*]

The Court found the verdict to be supported by substantial evidence and concluded (at page 973) with a cautionary word :

As was said by the Supreme Court in *Fairmount Glass Works v. Cuy Fork Coal Co.*, 287 U.S. 474, 485, 53 S. Ct. 252, 255, 77 L. Ed. 439, 'Appellate courts should be slow to impute to juries a disregard of their duties, and to trial courts a want of diligence or perspicacity in appraising the jury's conduct.'

"An insurance company sought declaratory judgment that a liability policy had been canceled in *Frieze v. West American Insurance Co.*, 8 Cir., 1951, 190 F. 2d 381, also cited by the government. The Court of Appeals concluded that the right to cancel the policy did not exist because of failure to comply with statutory provisions covering cancellation, although those provisions had not been brought to the attention of the Trial Court, reversed judgment for plaintiff and remanded the cause to the District Court. The Court of Appeals stressed the fact that it was proceeding under an exception to the rule which ought to be sparingly applied.

"The government further cited *United States v. Certain Parcels of Land, etc.*, 5 Cir., 1945, 149 F. 2d 81, which also involved eminent domain. There the Court found (at page 82) that the case was :

[C]onducted throughout with complete disregard of the rules of proof governing in such cases * * *. That the case was wrongly tried throughout may not be doubted.

even though:

It is true enough that the counsel for the United States stood by doing nothing to prevent, if they did not add to, the resulting confusion, and that normally a judge may not thus be put in error. [citation omitted]

"In *Hardware Mutual Casualty Co. v. Chapman*, 7 Cir., 1959, 272 F. 2d 614, and *Commercial Credit Corporation v. Pepper*, 5 Cir., 1951, 187 F. 2d 71, also cited by the government, the published reports indicate that motions for directed verdicts were filed in the course of the trials.

"In *Complete Auto Transit, Inc. v. Floyd*, 5 Cir., 1958, 249 F. 2d 396, the Court said (at page 399):

Our reversal of the judgment of the court below is based upon the error committed by the court below in denying appellant's motion for new trial based upon the legal excessiveness of the verdict of the jury. * * * The granting or refusing of a new trial is a matter resting within the sound discretion of the trial court exercised with regard to what is right and in the interest of justice; but that discretion is subject to review by the appellate court when it feels that injustice has resulted from the action of the lower court because of its conviction that the verdict was excessive as a matter of law and not merely as a matter of fact.

"In *Indamer Corporation v. Crandon*, 5 Cir., 1954, 217 F. 2d 391, the jury was allowed to hear an improper contention that plaintiff had been paid \$50,000 by a foreign insurance company and had no interest in the case, where the prejudicial effect of the statement was fully known to counsel making it. The monetary award was characterized by the Appellate Court as a small fraction of the loss as proved by the plaintiff and as testified to by a disinterested witness. The cause was remanded for a new trial limited to the issue of damages alone.

"*Georgia-Pacific Corporation v. United States*, 5 Cir., 1959, 264 F. 2d 161, was a tax case. The Fifth Circuit found (at page 164) that:

The sole controversy was over whether, as plaintiff contended, the stipulated and undisputed facts were such that taxpayer was entitled to a cost base for the timber, the sale of part of which brought about the tax controversy in this case, measured by the value placed upon the timber when the stock purchase was made, * * *.

The government also contended below that there was no real issue of fact in the case as to the occurrences described in the evidence, but it insisted that, as matter of law, the last transaction, the statutory merger, was not a component step in a multiple step transaction but an independent transaction, which established the base as contended for by the commissioner.

At the conclusion of the evidence, the Trial Judge overruled the government's motion for a directed verdict and inquired whether plaintiff desired to move for a directed verdict. Plaintiff, however, thought the matter would be best disposed of by a verdict. The Court then gave instructions to the jury, to which the government objected as virtually directing a verdict for plaintiff.

When, contrary to the general expectation, the jury returned a verdict for the United States, the plaintiff moved for a new trial on the ground that the verdict was without evidence to support it and manifestly unjust, and, this motion denied, appealed from the judgment presenting here a single specification of error. This is: that there was a complete lack of evidence to support the verdict; that it was, therefore, manifestly unjust and in excess of the powers of the jury and may not stand; * * * [page 165]

The Fifth Circuit found that refusal to grant a new trial under the circumstances was a clear abuse of discretion.

"In *Charles v. Norfolk & Western Ry. Co.*, 7 Cir., 1951, 188 F. 2d 691, this Court stated (at page 692) that:

Since plaintiff made no motion for directed verdict she may not, on appeal, challenge the sufficiency of the evidence to support the verdict for defendant. [citations omitted] The appeal, however, does present a serious question whether under the circumstances disclosed by the record she was entitled to a new trial.

This Court found that the Trial Court had given an erroneous instruction, over plaintiff's objection. Other instructions to which objection had not been raised were misleading and confusing. Further, the Trial Judge had himself expressed dissatisfaction with the verdict indicating that he felt an injustice had been done. The erroneous instruction imposed a burden of proof on plaintiff which was not required by the applicable law. This Court thought this was an exceptional case in which there had been a miscarriage of justice.

"In *Hamblen v. Kazlauski*, 7 Cir., 1958, 259 F. 2d 754, both parties cited the rule of this Circuit, as announced by Judge Duffy in *Irvin Jacobs & Co. v. Fidelity & Deposit Co. of Md.*, 1953, 202 F. 2d 794, 799:

Prior to the time that the jury returned its verdict the plaintiff did not move for a directed verdict or otherwise question the sufficiency of the evidence to support a verdict if returned in favor of the defendant. Under well established principles, the sufficiency of the evidence to support the verdict is not preserved for review * * * [citations omitted] unless this is one of those exceptional cases [citations omitted] which render inapplicable the general rule.

We did not find *Hamblen* to be such an exceptional case. Nor do we find that the case before us falls within the scope of the exceptions exemplified by the above cited cases on which the government relies.

"The government's motion for a new trial was addressed to the sound discretion of the Trial Court. The sole basis for the motion was the asserted lack of evidence to support the verdict.

"The government had the burden of proving the allegations of its Libel of Information by a preponderance of the evidence. The government introduced three medical witnesses, all of whom described studies which they had conducted with the accused product, Slim-Mint, and from which they concluded that it would not depress appetite, as claimed for it, and thus effect weight reduction.

"Dr. Leon S. Hirsh described the problems of obesity, and the operation of appetite as a function of memory. He testified that one must use up 3600 more calories than one receives in order to lose one pound, and that one, therefore, could not lose three to nine pounds per week without total fast and starvation, or lose five to twenty pounds 'fast.' He thought that the absorption by the stomach of the small quantity of benzocaine contained in Slim-Mint would be nil, and that its local anesthetic effect in the mouth would be negligible. Drs. Herbert Kupperman and Sam William Kalb both testified that even if some of the ingredients of Slim-Mint, such as benzocaine, oil of wintergreen and oil of peppermint (which are local anesthetics) might dull the taste buds, that would still not control appetite. All three doctors characterized the advertised claims for Slim-Mint as false. Dr. Kalb said that the promotional pamphlet promised reduction without dieting, but that the insert in the package did in fact prescribe a diet.

"The government and claimant differ on the proper definition of diet in this connection. The government quoted the definition contained in the American Illustrated Medical Dictionary:

The customary allowance of food and drink taken by any person from day to day.

The claimant contends that on that definition all persons at all times are dieting. Claimant's witness Dr. Loesch defined 'diet' as follows:

Diet would be a specialized prescribed regime of a stated composition and listed ingredients. * * * For different types of patients you would prescribe different diets. For cardiac patients you might prescribe a low

salt diet. * * * It is a given composition for a given distribution of food with quite fixed values of what a person should have.

The insert of which the government complains recommends good eating habits. Examples include: 'Don't tempt yourself with fattening foods on the table.' 'Eliminate the use of salt * * *' 'Learn to like the natural flavor of food without butter, cream, or mayonnaise.' 'Avoid fried foods * * *' Each day you should eat two portions of broiled or boiled lean meat or fish. Two boiled or poached eggs or a portion of any cheese may be substituted for the meat. Eat fresh fruits and vegetables, raw if you like.' Claimant's expert witnesses said that this general instructional sheet was not a 'diet.'

"The testimony of the government's expert witnesses was subjected to attack on cross-examination and through contrary testimony of claimant's witnesses. For example, on cross-examination, defense counsel elicited testimony regarding the nature of the studies made, with a view to showing poor selection of participants, instruction given them which differed from that contained in the Slim-Mint packages, inadequate record-keeping and controls to ensure accuracy of testing. The three doctors testified further as to their own medical and pharmacological experience with obesity and their own theories on its treatment. One doctor, for instance, indicated what the jury could have regarded as a bias against all self-medication. Claimant's witness Professor Kenneth Alexander Brownlee characterized Dr. Kupperman's records as inconsistent and inaccurate. The government's expert witnesses also criticized each other's tests.

"Claimant's three expert witnesses, Drs. L. A. Nalefski, Arnold E. Weyman and Frederick A. Treffer, testified regarding their tests. They found Slim-Mint was an aid to appetite control. The government argues that none of these doctors could explain exactly how and why the drug worked. However, they did report successful results. Dr. Loesch suggested a possible theory involving oral gratification as a substitute for food.

"Several lay witnesses testified to their own loss of weight while using Slim-Mint. They said they ate as much as they wanted to eat, but found themselves wanting to eat less than before. One witness said he lost twenty pounds in about six months, which he considered 'fast.' Another testified to a loss of thirty-eight pounds in about five months. A third testified to losing twenty-five pounds in a single month.

"The jury here could reasonably have found that there was a lack of credible and reliable evidence adduced by the government to sustain its burden of proof. We conclude that the District Judge did not abuse his discretion in denying the motion for new trial. The judgment of the District Court is affirmed."

Thereafter, the Government petitioned for a rehearing, which petition was denied, on 4-9-62.

7582. Vitamin and mineral supplements, brewer's yeast tablets, and dehydrated cabbage tablets. (F.D.C. No. 46568. S. Nos. 85-026/7 R, 45-014/16 T.)

QUANTITY: 284 90-tablet btl., 97 200-tablet btl., and 3 600-tablet btl., of *Toddlers vitamin and mineral supplement*; 60 100-tablet btl. and 6 300-tablet btl., of *Vita-Glo food supplement*; 23 ctns., each containing 3 200-tablet btl., of *Nutra-Glo food supplement*; 248 100-tablet btl. and 62 250-tablet btl. of *brewer's yeast tablets*; and 57 btl. of *dehydrated cabbage tablets*, at Varna, Ill., in possession of Century Foods Co.

SHIPPED: Between 5-8-61 and 7-3-61, from Kalamazoo, Mich., and Huntington Park, Calif.

LABEL IN PART: (Btl.) "Toddlers Vitamin and Mineral Supplement for Children Ages 2 to 12 Each three tablets contain the following * * * Manufactured for Century Laboratories Varna, Illinois 123"; "Vita-Glo Food Supplement A Multiple Vitamin and Mineral Supplement with Added Protein Manufactured for Century Laboratories, Varna, Illinois"; "Century 'Nutra Glo' A

Dietary Food Supplement Tablets Manufactured for Century Laboratories, Varna, Illinois A daily ration of six Nutra-Glo tablets contain: * * *"; "Century Brewer's Yeast Tablets * * * 7½ grain Made of a fine strain of debittered dried yeast containing all of the factors of the B Complex found naturally in Yeast and can be truly called a natural B Complex Tablet. Directions: As a Food Supplement * * * Century Laboratories, Varna, Illinois"; "Century Natural Pure Dehydrated Cabbage 300 9-grain Tablets Manufactured for Century Laboratories, Varna, Illinois Directions: Two or more Tablets before meals six per day."

ACCOMPANYING LABELING: Booklets entitled "The Unseen Menace to Health"; leaflets entitled "An Important Message to Mothers of 2's to 12's," "Life Depends On Minerals and Vitamins" and "The Chemical Ingredients of a Balanced Diet"; sales kits containing a paperback book entitled "Eat Live and Be Merry" by Carlton Fredericks, a booklet entitled "The Unseen Menace to Health," leaflets entitled "An Important Message to Mothers of 2's to 12's" and "See What The Lack Of One or More Vitamins Might Mean"; and an unknown number of repack labels for the *brewer's yeast tablets* and *dehydrated cabbage tablets*.

RESULTS OF INVESTIGATION: The articles, other than the Nutra-Glo tablets, were shipped in bulk as described above and repacked into bottles by the Century Foods Co. The accompanying labeling was used by such company in promoting sales of all of the articles.

LIBELED: 10-10-61, S. Dist. Ill.; amended libel 10-31-61.

CHARGE: *Toddlers vitamin and mineral supplement, Vita-Glo food supplement, and Nutra-Glo food supplement*, 502(a)—while held for sale, the labeling, namely, the above-mentioned booklets and leaflets, contained false and misleading representations that the articles were adequate and effective for the treatment and prevention of infections in, and improper functioning of, all parts of the body; conjunctivitis, nervousness, nerve disorders, indigestion, spastic colon, degeneration of bone marrow, lesions of skin and eyes, liver disease, colds, anemias, dental caries, lowered resistance against tuberculosis, and pus formation; to promote vigorous health and strength; balance the nutritional needs of the body; and promote growth and longevity.

Brewer's yeast tablets, 502(a)—while held for sale, the labeling, namely, the bottle label, the above-mentioned booklets, and the leaflets entitled "See What The Lack of One Or More Vitamins Might Mean" and "The Chemical Ingredients of a Balanced Diet," contained false and misleading representations that the article was adequate and effective for the treatment and prevention of loss of appetite, impaired nutrition, loss of weight, constipation, nervous disorders, insomnia, liver disease, lesions of skin and eyes, enlarged heart, and spastic colon.

Dehydrated cabbage tablets, 502(a)—while held for sale, the labeling, namely, the above-mentioned booklets and the leaflets entitled "An Important Message to Mothers of 2's to 12's," contained false and misleading representations that the article was of significant value for special dietary supplementation and was adequate and effective for the treatment of ulcers.

Toddlers vitamin and mineral supplement, Vita-Glo food supplement, Nutra-Glo food supplement, and brewer's yeast tablets, 502(a)—while held for sale, the labeling, namely, the paperback book entitled "Eat, Live and Be Merry" by Carlton Fredericks, contained false and misleading representations that the articles were adequate and effective for the treatment and prevention of dis-

eases of the liver and gall bladder; peptic ulcer, diarrheal diseases, intestinal tuberculosis, mental disorders, heart failure, pulmonary disease, diabetes mellitus, chronic alcoholism, loss of protein in myelitis and nephrosis, rheumatoid arthritis, arthritis, rheumatic fever, rheumatic heart disease, cancer, leukemia, cystic mastitis, and kidney disease; and that Carlton Fredericks is "America's Foremost Nutritionist"; and that the book furnishes scientifically proven nutritional and medical guidance for the supplemental use of vitamins and minerals by individuals, generally, in the treatment and prevention of serious diseases.

DISPOSITION: On 3-30-62, Carlton Fredericks filed a motion and petition to intervene in the libel action and, on 5-1-62, the court granted such motion. Thereafter, the intervenor filed a motion for a more definite statement of the libel in certain particulars, which was denied by the court on 7-10-62. The intervenor then filed an answer to the libel and served written interrogatories upon the Government. The Government filed a motion to strike portions of the intervenor's answer, objections to some of the intervenor's interrogatories, and answers to the remainder of the interrogatories. On 1-10-63, the court handed down the following decision with respect to the Government's motion to strike and objections to interrogatories (32 F.R.D. 32) :

MERCER, District Judge: "This case is a libel of information by the United States against divers vitamin and mineral compounds offered for sale by Century Food Company after shipment in interstate commerce, alleging that each such article of drug is misbranded. Misbranding is alleged to arise from the fact that various pamphlets and articles of literature accompanying the several drug products contain false and misleading representation as to medical guidance for the use of vitamins and minerals in the cure of serious diseases. One such book alleged to constitute a false labeling of the drug products is a paperback book entitled, 'Eat, Live and be Merry,' written by the intervenor, Carlton Fredericks.

"Fredericks intervened in the cause pursuant to an order of this court and filed an answer to the libel, as amended. The cause is now before the court upon the libellant's motion to strike certain portions of the intervenor's answer and the intervenor's four affirmative defenses.

"It seems apparent from the briefs directed to this motion, that there may exist some misconception as to the issue presented by this libel. In view of that misconception, I think it wise at the outset to articulate the issue involved in this case, insofar as it relates to the intervenor's book. The only issue before the court, in that regard, is the question whether the intervenor's book is being used by Century as labeling for the accused drug products, and, if so, whether that use of the book as labeling constitutes false and misleading representations and misbranding. If the books seized are so used with that effect, then the book, to the extent of that use as a labeling for Century's products, is subject to seizure and condemnation by the Food and Drug Administration. *United States v. 8 Cartons, etc., Molasses*, W.D.N.Y., 103 F. Supp. 626.

"The merits of intervenor's book, as a book, are not an issue in the case. In like manner, intervenor's competency and integrity as an authority on nutrition is not an issue.

"With the issues so defined, it is clear that the averments of the answer and the affirmative defenses to which the motion to strike is directed are, with one exception to be noted, irrelevant to the issues in this case.

"Paragraph 2(E) of the answer is in the following language :

[Intervenor] denies the allegations of the final paragraph of the amendment to the libel of information, and alleges further that these allegations are defective since, on their face, they do not purport to relate to the seized articles but rather directly challenge the merits of the book itself and the professional competence of Fredericks personally.

"The Government moves to strike all of that paragraph, except the first 15 words which deny the allegations of the libel. That motion is well taken. The paragraph of the amended libel to which the motion relates asserts in summary, the misbranding of the drug products by the use of the intervenor's book, because of representations therein contained that intervenor is America's foremost nutritionist, and that the book furnishes scientifically proven nutritional and medical guidance for the supplemental use of vitamins and minerals, generally, in the treatment and prevention of serious diseases. Each of those statements and assertions is alleged to be false and misleading. Issue is joined by the denial of those allegations.

"As I have pointed out above, neither intervenor's professional competency nor the merit of the book, 'Eat, Live and Be Merry,' as a book, is an issue in this case. To the extent that they enter the case at all, these facts are a part of the Government's proof of misbranding, once the Government has sustained the burden of showing that the book was used as a label for these drug products. All of paragraph 2 of the answer, except the denial of the libel allegations contained in the first 15 words of that paragraph, are irrelevant to any issue in this case and should be stricken.

"Paragraph 3 of the answer alleges, in summary, that the intervenor had no knowledge of the nature of the seized drug articles or of the operation of Century, that Century's use of intervenor's book to sell or promote the seized articles was not authorized by intervenor, that intervenor had no knowledge of the efficacy of the seized articles for the treatment of any disease, and that over 20,000 copies of intervenor's book have been sold through book stores and other outlets to the public.

"Each of those averments of fact is completely irrelevant to any issue in this case. In fact, a fair reading of the libel imports the implication that intervenor was not culpable in the premises alleged. Certainly there is no allegation in the libel that intervenor had any knowledge of Century's operation, or drug products, or that intervenor's book was used as labeling for those products by his authority. If it be assumed that intervenor had no knowledge of Century's operation, and had not authorized Century's use of his book as labeling for its drug products, copies of intervenor's book would, nevertheless, be subject to seizure to the extent that they were used and are being used as false labeling for Century's products. And the fact of the matter as to whether one copy, twenty thousand copies, or twenty million copies of intervenor's book have been sold to the public is a fact which is simply wholly alien to the case at bar. Paragraph 3 of the answer will be stricken.

"Intervenor's first affirmative defense alleges, in substance, that the libel of information, as amended, fails to allege any basis upon which intervenor's book can be seized.

"Frankly, I fail to see that the first affirmative defense adds anything to intervenor's answer which had not previously therein been accomplished by the denial of the allegations of the libel, as amended. To me, the first defense is merely repetitious of the denial of the truth of the allegations of the libel. However, that defense is not subject to objection and the Government's motion to strike the first affirmative defense is without merit.

"Intervenor's second affirmative defense avers that the seizure of intervenor's book in connection with this case constitutes a prior restraint in violation of the First Amendment to the Constitution of the United States.

"The third affirmative defense avers that the seizure of intervenor's book in this case exceeded the authority granted to the Government by the Federal Food, Drug & Cosmetic Act.

"The Act prohibits false labeling and misbranding, and authorizes the seizure of articles which are so misbranded. Certainly, the Act contemplates that a book, as well as any other type of representation, may be so used as to become a label for an article offered for sale. It was so held in *United States v. 8 Cartons, etc., Molasses, supra*, in which the court entered a judgment of condemnation against a book to the extent that it was used as a label for the sale of a brand of blackstrap molasses. The same case resolved the issue of the constitutionality of that seizure, the court holding that the First Amendment does not prohibit the seizure and condemnation of a book which was

being used as prohibited labeling. The court was careful there to point out that the condemnation related to the use of the book for that purpose, only, and that it could not operate as a restraint upon the sale of the book through book stores or other outlets. As the court there suggested, the condemnation did not prohibit the sale of the book in food stores, and even in stores in which the brand of molasses involved was offered for sale, so long as the book was not offered in conjunction with the product as a label for the product.

"Measured by the statute and by the decision in the *Molasses* case, which I approve, neither the second nor the third affirmative defenses states a defense to the libel in this case.

"The Fourth affirmative defense is in the following language:

As evidenced by the Food and Drug Administration's press release on the seizure, attached to the answer as Exhibit A, which the Food and Drug Administration widely disseminated, the seizure of the book 'Eat, Live and be Merry' constituted an illegal attempt to challenge personally the competence of its author, Carlton Fredericks, and the merits of statements contained in the book.

"Exhibit A attached to the answer is a press release of the Food and Drug Administration dated Saturday, November 25, 1961, relating to the filing of this libel, which quotes part of the libel with reference to intervenor's book.

"The defense will be stricken. The fact that the Food and Drug Administration, did or did not issue a press release related to this seizure, regardless of whether statements contained in any such press release are accurate or inaccurate in their reference to intervenor's book, is wholly immaterial to any issue which can properly be raised in this case. Even if it be assumed, as I do not assume, that the Food and Drug Administration acted with some ulterior motive in issuing the press release of which complaint is made, that has no bearing upon the decision of the case at bar. The issue is a simple one, whether the drug products sought to be condemned by the libel were misbranded by the use, among other things, of intervenor's book as labeling.

"It is hereby ordered that the motion by the United States to strike the first affirmative defense is overruled. The motion by the United States to strike a part of paragraph 2(E) and paragraph 3 of the answer and to strike the second, third and fourth affirmative defenses is allowed.

"The cause is presently before the court, also, upon the objection by the United States to interrogatories numbered 16 through 19, inclusive, proposed by the intervenor. Each of these interrogatories requests the United States to explain the basis for statements contained in the press release to which illusion has hereinabove been made. Thus each of the interrogatories to which objection is made is irrelevant to the issues in this case and the objection thereto should be sustained.

"As hereinabove suggested, the subject matter of this suit is the articles of drugs and the labeling material seized by the Government, and the issue to be presented to the court is the question whether the labeling material misbrands the subject drugs by any false or misleading statements therein contained. See, *United States v. 3 Unlabeled, 25 Pound Bags Dried Mushrooms*, 7 Cir., 157 F. 2d 722. The press release has no relevancy to that issue, and interrogatories delving into the basis for statements made in that press release cross over into the field of the ridiculous.

"The objections by the United States to intervenor's interrogatories 16, 17, 18 and 19, are sustained."

In view of the court's decision of 1-10-63, and without admitting that the book "Eat, Live and Be Merry" misbranded the article under seizure, the intervenor, on 3-25-63, withdrew from the case. Thereafter, on 3-25-63, the court entered a default decree of condemnation and ordered that the articles be destroyed except for the books seized which were ordered to be delivered to the Food and Drug Administration.

7583. Vitamin C "400" tablets and Super-Amino tablets. (F.D.C. No. 46941. S. Nos. 15-349/50 T.)

QUANTITY: 12 cases, each containing 12 250-tablet btls. and 12 600-tablet btls., of *Vitamin C "400" tablets*; and 6 cases, each containing 24 225-tablet btls., and 14 cases, each containing 12 450-tablet btls., of *Super-Amino tablets*, at Shepherdsville, Ky., in possession of Publisher's Printing Co.

SHIPPED: Between 10-6-61 and 11-28-61, from New York, N.Y.

LABEL IN PART: (Btl.) "Mother Nature's Richest Source of Natural Vitamin C plus Natural Citrus Bioflavonoid Complex Natural Vitamin C '400' with Acerola Every tablet contains Acerola Universal Nutritions, Inc., Dist. New York 13, N.Y. Directions * * * Each tablet contains 400% of the minimum daily requirement of Natural Vitamin C from Wild Rose Hips and Acerola (Barbados Cherries) .5 mg. Natural Citrus Bioflavonoid Complex" and "Universal Nutritions * * * Super-Amino 10 Grain Tablets * * * A combination of Calcium Caseinate, Skim Milk Powder, Malt and Malted Milk Powder * * * so formulated to provide a palatable and tasty source of amino acids * * * Universal Nutritions, Inc., Dist. New York 13, N.Y."

ACCOMPANYING LABELING: Newspaper-type mailing pieces entitled "Universal Nutrition Spectacular 1¢ Sale Edition."

RESULTS OF INVESTIGATION: The articles were packed and shipped by the dealer, Publisher's Printing Co., to persons on lists furnished by John Lust of Benedict Lust Publications and Lust's Health Food Store, New York, N.Y. The articles were invoiced to the dealer by Universal Nutritions, Inc., New York, N.Y. The accompanying literature, which was provided by Universal Nutritions, Inc., was mailed to persons on mailing lists supplied by Mr. Lust.

LIBELED: 1-30-62, W. Dist. Ky.

CHARGE: *Vitamin C "400" tablets*, 502(a)—when shipped and while held for sale, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective for the treatment and prevention of stiff joints, rheumatic pains, asthma, allergies, bleeding gums, hardening of the arteries, weak blood capillaries, slow wound healing, poor resistance to disease, lack of vitality, and nutritional anemia.

Super-Amino tablets, 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective in the treatment and prevention of great fatigue, loss of strength and pep, depression, and vague aches and pains; and for promoting youthful strength, energy, firm, healthy tissue, gland repair, enzyme and hormone production, resistance to disease, vigorous health, and body building; antibodies to fight disease, including infections, bacterial and virus diseases; red, fighting blood, long life, bone cell and bone development, heart tissue growth and heart cycle action, and to maintain brain tissues in later life; that the article was of significant value as a source of protein for special dietary supplementation; that the body needs all the essential amino acids in the article every day at every meal; and that the nutritional protein requirements for people over 40 are different than those of adults, generally.

DISPOSITION: The article was claimed by Universal Nutritions, Inc., New York, N.Y. The case was transferred to the District of New Jersey, on 3-20-62. On 1-15-63, the claimant consented to a decree of condemnation without admitting the allegations of the libel, and the articles were destroyed.

7584. Enzyme compound tablets, Tinc Zoin benzoin compound aerosol, and Vita 50 capsules. (F.D.C. No. 48246. S. Nos. 60-294 T, 60-296/7 T.)

QUANTITY: 3 78,000-tablet drums, 1 35,000-tablet drum, 804 100-tablet btl., and 439 30-tablet btl., of *enzyme compound tablets*; 750 6-oz. cans of *Tinc Zoin benzoin compound aerosol*; and 83 100-capsule btl. of *Vita 50 capsules*, at Jackson, Miss., in possession of Taylor Laboratories, Div. of Dumas Milner Corp.

SHIPPED: Between 8-30-61 and 6-18-62, the *enzyme compound tablets* from St. Louis, Mo., by K-V Pharmacal Co., the benzoin compound from Arlington, Tenn., by Aerosol Corp. of the South, and the *Vita 50 capsules* from Detroit, Mich.

LABELS IN PART: (Drum) "D-M Vitamin-Digestive Enzyme Compound Each tablet contains * * * A Dietary supplement * * * K-V Pharmacal Company * * * St. Louis 17, Missouri To Dumas Milner Corp. * * * Jackson, Miss."; (btl. and ctns.) "Replenz Digestive Enzymes With Vitamins and Minerals Aids Digestion * * * Taylor Laboratories, Div. of Dumas Milner Corp. Jackson, Miss. * * * Each tablet contains * * * Enzymes * * * Vitamins * * * Minerals"; (can) "Tinc Zoin Benzoin Compound Tincture U.S.P. Aerosol For External Use Antiseptic—Protectant Taylor Laboratories, Division of Dumas Milner Corp. Jackson, Miss."; and (btl.) "Vita 50 Vitamin A 50,000 Units * * * Taylor Laboratories, Div. of Dumas Milner Corp. Jackson, Miss."

ACCOMPANYING LABELING: Leaflets entitled "Replenz Digestive Enzymes With Vitamins and Minerals"; window streamers entitled "Stomach Trouble"; display cartons reading in part "Over 40 Stomach Troubles"; and additional bottle, can, and carton labels.

RESULTS OF INVESTIGATION: The *enzyme compound tablets* in the 30-tablet bottles had been shipped in the bulk drums and repacked by the dealer. The *Vita 50 capsules* had been shipped in bulk drums and had been repacked by the dealer into bottles.

LIBELED: 10-22-62, S. Dist. Miss.

CHARGE: *Enzyme compound tablets*, 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective for aiding the digestive process, dyspepsia, food intolerance, belching, flatulence, "over 40 stomach trouble," stomach trouble, stomach distress due to enzyme deficiency, gas, heartburn, and lack of vitamins due to impaired intestinal absorption.

Tinc Zoin benzoin compound aerosol, 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as to treatment for small fissures, cracked nipples, and indolent ulcers.

Vita 50 capsules, 502(a)—while held for sale, the labels of the article contained false and misleading representations that the article was adequate and effective as a treatment for dry skin, acne, eczema, and to improve resistance to infections.

DISPOSITION: 3-16-63. Default—destruction.

7585. Various products containing royal jelly, safflower oil, or lecithin. (F.D.C. No. 48086. S. Nos. 68-575/7 T, 68-579/80 T.)

QUANTITY: 15,000 capsules and 88 100-capsule btl. of *ViViBx Formula No. 190*; 64,000 capsules and 72 70-capsule btl. of *ViViBx Formula 152-A*;

40,000 capsules of 76 100-capsule btl. of *ViViBx Formula No. 80-A*; 22 30-capsule btl. of *Rojelan royal jelly capsules*; and 197 30-capsule btl. of *ViViBx Formula No. 160*, at Chicago, Ill., in possession of Frederick Herrschner.

SHIPPED: Between 3-29-62 and 7-7-62, from Detroit, Mich., Newark, N.J., and Brooklyn, N.Y.

LABELS IN PART: (Btl.) "*ViViBx Formula No. 190 Safflower Oil Capsules with Vitamin B-6* * * * Sole Distributors Frederick Herrschner * * * Chicago 7 Each Gelatine Capsule Contains: Safflower Oil 912 Mgm. * * * Vitamin B-6 0.5 Mgm."; (btl.) "*ViViBx Formula No. 152-A A planned dietary aid in the prevention and lowering of body cholesterols* * * * Sole Distributors Frederick Herrschner * * * Chicago 7 * * * Two capsules contain: Essential unsaturated fatty acids (Linoleic acid from 1090 Mgm. of genuine Safflower oil) . . . 764 Mgm. Pyridoxine HCL . . . 5 Mgm. Vitamin E * * * 10 I.U. Niacin (Nicotinic acid) . . . 200 Mgm."; (btl.) "*ViViBx Formula No. 80-A Lecithin With Vitamins A and D Each capsule contains* * * * Sole Distributors Frederick Herrschner * * * Chicago 7"; (btl.) "*Rojelan Improved Formula Double Strength Royal Jelly Capsules A Natural Food Supplement Fortified with Vitamins, Minerals, Enzymes, and Lipotropic Factors* * * * Rojelle Pharmacal Co. * * * Chicago * * * Each Tablet Contains: * * * Royal Jelly 50 Mgm." and (btl.) "*ViViBx Formula No. 160 Double Strength Royal Jelly Capsules* * * * Frederick Herrschner * * * Chicago 7 * * * Each Tablet Contains: * * * Royal Jelly 50 Mgm."

ACCOMPANYING LABELING: Catalog entitled "Our 20th Anniversary 40th Semi-annual Sale"; folder entitled "Is Royal Jelly a Miracle Substance"; mailing piece entitled "3 Powerful reasons to buy Rojelan Royal Jelly Capsules"; leaflet entitled "Medical Research Proves Value of Royal Jelly"; and various extra bottle labels as described above.

RESULTS OF INVESTIGATION: All the articles, except the royal jelly capsules, had been shipped in bulk cartons and had, in part, been repacked by the dealer into bottles bearing his own labels. The literature described above as accompanying labeling was used in promoting sales of the articles.

LIBELED: 9-5-62, N. Dist. Ill.

CHARGE: 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that *ViViBx Formula No. 190* was adequate and effective to lower cholesterol, and for the treatment and prevention of hardening of the arteries (arteriosclerosis) and coronary artery disease; and was of unusual significance for special dietary supplementation and therapeutic use by reason of the presence therein of safflower oil; that *ViViBx Formula No. 152-A* was adequate and effective to prevent, lower, and control blood cholesterol and for the treatment and prevention of heart attacks (coronary thrombosis), hardening of the arteries (arteriosclerosis), to feel buoyant, and to avert the problems of aging; and was of unusual significance for special dietary supplementation and therapeutic use by reason of the presence therein of safflower oil; that *ViViBx Formula No. 80-A* was adequate and effective to digest and metabolize fats; to reduce serum cholesterol; and for the treatment and prevention of hardening of the arteries and cardiovascular diseases; that *Rojelan royal jelly capsules* were adequate and effective to promote sexual potency, prolong life, promote the vital function of life, rejuvenation, general vitality, and health; was a super food for the very tired, fatigued, convalescent, and depressed individuals; and was of significant

and vital value for special dietary supplementation and therapeutic use by reason of the presence therein of royal jelly, choline bitartrate, inositol, methionine, glutamic acid, lemon bioflavonoid complex, rutin, desiccated liver, potassium sulfate, para-aminobenzoic acid, yeast hydrolysate, biotin, soya bean lecithin, wheat germ oil, magnesium sulfate, manganese sulfate, watercress, parsley, kelp, red bone marrow, alfalfa, and rose hips; and that *ViViBx Formula No. 160*, by reason of the presence therein of royal jelly, was adequate and effective for geriatric use to promote return of lost appetite, gain in weight, a state of euphoria, well-being, and buoyancy, to lessen nervous tension, and to promote sexual potency; and was of significant and vital value for special dietary supplementation and therapeutic use by reason of the presence therein of royal jelly, choline, bitartrate, inositol, methionine, glutamic acid, lemon bioflavonoid complex, rutin, desiccated liver, potassium sulfate, para-aminobenzoic acid, yeast hydrolysate, biotin, soya bean lecithin, wheat germ oil, magnesium sulfate, manganese sulfate, watercress, parsley, kelp, red bone marrow, alfalfa, and rose hips.

DISPOSITION: 5-13-63. Default—destruction.

7586. Color-lamp components. (Inj. No. 380.)

COMPLAINT FOR INJUNCTION FILED: 5-20-60, S. Dist. Calif., against Stanley A. Burroughs, Riverside, Calif.

NATURE OF BUSINESS: The defendant operated a business under the name of Burroughville Specialties, at Arlington, Calif., and through lectures and the dissemination of literature, he was engaged in the business of promoting the sale of *color-lamp components*, each of which was a device within the meaning of Federal Food, Drug, and Cosmetic Act.

The devices consisted of lamp bases, lamp shades, light bulbs, and colored plastic slides. The defendant obtained the lamp bases and colored plastic slides from sources outside the State of California, and the lamp shades and light bulbs from within the State of California, though these components may also have had an out-of-state origin. The defendant did not assemble the components, but sold and distributed sets of the unassembled components to customers within and outside of the State of California, so that each customer could then assemble the color-lamp for himself.

The defendant distributed two items of literature in conjunction with his promotion of the devices; one item was a book entitled "Living Creatively Through Vita-Flex, Color Vibration and Nutrition" and the other was a booklet entitled "The Master Cleanser." The book and booklet constituted the labeling of the devices since they accompanied them, described the defendant's theory of color therapy, and stated directions for using the devices for therapeutic purposes.

ALLEGED VIOLATIONS: The complaint alleged that the defendant shipped into interstate commerce, the devices accompanied by the above labeling, and that, when the defendant held the devices for sale after shipment in interstate commerce, he also caused the labeling to accompany the devices.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the articles contained the following false and misleading representations:

A. That all systems of healing depend upon color and the chemical action in the body which produces color, to bring about any kind of change in the body functions;

B. That color gives the body the spark of power to perform its own healing processes;

C. That the scientific application of color to the body introduces a natural force that enables the body to eliminate waste and congestion;

D. That the scientific application of color is the most natural source of healing that has ever been used;

E. That use of the devices to project twelve specific colors (red, yellow, orange, lemon, green, turquoise, blue, indigo, violet, scarlet, purple, and magenta) upon the body at different times will stimulate the liver, build the red principle of the blood, stimulate the various senses, stimulate and build the lungs, activate the thyroid and depress the parathyroid, aid in assimilation of proper food for better nutrition, alleviate paralytic strokes and infantile paralysis, act as an anthelmintic, provide proper elimination of mucous and body waste, treat all chronic disorders, dissolve blood clots to prevent stoppages in the head and heart, treat fever and serious burns or other destruction of the skin, act as a sedative and bring relief from swellings and acute pain, control hemorrhages and excess discharges, relieve dysentery and diarrhea, provide sedation for violent mental conditions, increase blood pressure and circulation, relieve asthma and sinus conditions, reduce blood pressure, relieve toothache, provide all kinds of desirable changes for heart conditions, and balance the sex desires of both sexes; and

F. That the device was a necessary adjunct to the adequate and effective treatment of boils, abscesses, carbuncles, eczema, all types of weeping or dry sores anywhere on the body, cancer, leukemia, tumors, varicose veins, hemorrhoids, glaucoma, phlebitis, colds, influenza, "virus X," measles, whooping cough, scarlet fever, pneumonia, bronchial disorders, all diseases of the eyes, nose, and throat, arthritis, rheumatism, bursitis, neuritis, constipation, anemia, asthma, hay fever, sinusitis, tuberculosis, and all other diseases which affect the body of man.

502(f) (1)—the complaint alleged that the defendant would, unless enjoined, distribute the devices without labeling stating the conditions and purposes for which they were intended and that, therefore, the labeling of the devices would fail to bear adequate directions for use because of the omission therefrom of a statement as to the conditions and purposes for which the devices were intended.

DISPOSITION: 6-7-60. Consent—the decree permanently enjoined the defendant from directly or indirectly doing any of the following acts with respect to any lamp bases, lamp shades, light bulbs, and colored plastic slides, regardless of whether they were separate unassembled components or whether they were assembled units or with respect to any similar devices, or with respect to any device intended for similar purposes:

A. Causing to be introduced or delivered for introduction into interstate commerce, any of such devices which was misbranded within the meaning of 502(a) or 502(f) (1) because it

1. was accompanied by the book entitled "Living Creatively Through Vita-Flex, Color Vibration and Nutrition"; or was accompanied by the booklet entitled "The Master Cleanser"; or was accompanied by any written, printed, or graphic matter substantially to the same effect; or

2. bore or was accompanied by any written, printed, or graphic matter which contained the false and misleading representation described above; or

3. failed to state in its labeling all of the diseases, conditions, symptoms, and purposes for which the device was intended to be used and for which it was represented, by any means, to the public; and

B. Causing any act to be done with respect to any of the devices while the device was held for sale after shipment in interstate commerce, which act resulted in such device being misbranded within the meaning of 502(a) or 502(f) (1)

1. by being accompanied by the above written, printed, and graphic matter; or

2. by bearing or being accompanied by any written, printed, or graphic matter containing any of the representations or suggestions described above; or

3. by failing to state in its labeling all of the diseases, conditions, symptoms, and purposes for which such device was intended to be used and for which it was represented, by any means, to the public.

7587. Pulse-A-Rythm Massaging Mattress. (Inj. No. 410.)

COMPLAINT FOR INJUNCTION FILED: 10-10-61, S. Dist. Fla., against Pulsnation Enterprises, Inc., St. Petersburg, Fla., John R. Riley, secretary-treasurer, David J. Scott, general manager, and Margaret Austin, executive secretary. On 8-22-62, an amended complaint was filed to include as a defendant, Pulsatronics, Inc., the successor corporation to Pulsnation Enterprises, Inc.

NATURE OF DEVICE: The device was a regular spring-type mattress containing, near one end, a small off-center shaft driven by a 1/100 horsepower electric motor. The motor was designed to be connected to an ordinary electrical outlet either directly or through a coin box which operated the motor for 15 minutes at adjustable speeds for 25 cents.

ACCOMPANYING LABELING: A circular entitled "For the Best of Rest Pulse-A-Rythm Massaging Mattress"; a business reply card addressed to "Pulsnation Enterprises"; a leaflet bearing the words "Summer 1957 Season Directory for the Travelers of the Pulse-A-Rythm Route"; a circular entitled "Directory of Motels equipped with Massaging Mattresses"; a placard reading "All Tense From That Long Drive? Joints Tired and Sore Muscles Ache? Try our Pulse-A-Rythm Mattress"; copy of an article entitled "Shall We Provide Slumber Therapy" appearing in the June 1958 issue of the Southern Hotel Journal Magazine; copy of an article headed "New Guest-pleaser available to Congress Motels 'Pulse-A-Rythm' Massage Mattresses Now Obtainable on Share-the-Profit Plan" appearing in the publication entitled "Motor Hotel News"; copy of an article entitled "Sense in your advertising dollar" appearing in the January 1960 issue of the publication entitled "Western Motel"; copy of a testimonial letter, dated January 29, 1960, from Curt's Cottage Court, Rocky Mount, North Carolina; copy of a testimonial letter, dated October 20, 1960, from John M. Moore, Jr., general manager of Sea Ranch Court, Garden City, South Carolina; and copy of a testimonial letter, dated November 7, 1960, from the Confederate Inn and Colonial Court, Mississippi City, Mississippi.

CHARGE: The complaint alleged that the defendants were engaged in manufacturing, selling, and distributing in interstate commerce, a device designated by the name of *Pulse-A-Rythm Massaging Mattress* which was misbranded under 502(a) because of false and misleading representations in its labeling that the device was adequate and effective in the treatment of severe migraine, arthritis, rheumatism, bursitis, poor circulation and other ailments of the muscular, circulatory, and osteal (bony) systems.

The complaint alleged further that if the defendants were merely restrained from introducing the device into interstate commerce because of false and misleading labeling the defendants would not discontinue interstate distribution

of the device but would continue to ship it in interstate commerce without specifying in its labeling the purposes and conditions for which it was intended. In these circumstances the device would be misbranded under 502(f)(1), in that its labeling would not bear adequate directions for use because of the omission from its labeling of the purposes and conditions for which the device was to be used.

The complaint alleged further that the defendants had been warned on various occasions that the device was misbranded because of false and misleading labeling; that such warnings had been given by a previous seizure action and by four establishment inspections; and that despite such warnings the defendants continued to introduce the misbranded device into interstate commerce.

DISPOSITION: On 10-30-61, the defendants filed a motion to dismiss the complaint and, on 3-28-62, the motion was denied. An answer was filed by the defendants, on 4-16-62, denying that the device was misbranded. Interrogatories were thereafter served upon the defendants by the Government and by the defendants upon the Government and were subsequently answered. An amended complaint was also filed as indicated above. On 11-23-63, the defendants, Pulsnation Enterprises, Inc., Palsa-Tronics, Inc., and John R. Riley, having consented to the entry of a decree and having offered evidence and testimony as to the participation of Defendants David Scott and Margaret Austin in the acts complained of, the court entered a decree of permanent injunction against all of the defendants. The injunction enjoined all of the defendants against introducing into interstate commerce, the device designated as "*Pulse-A-Rhythm Massaging Mattress*," or any similar device which:

(a) is accompanied by the labeling alleged in the complaint or by any written, printed, or graphic matter substantially to the same effect;

(b) bears or is accompanied by any written, printed, or graphic matter which states, represents, suggests, or implies that such device is an adequate and effective treatment for severe migraine, arthritis, rheumatism, bursitis, poor circulation, and other ailments of the muscular, circulatory, and osteal (bony) systems, or which is otherwise false and misleading; and

(c) fails to bear labeling stating every disease, condition, symptom, and purpose for which such device is intended to be used and for which it is represented by any means to the public.

7588. Nemectron devices. (F.D.C. No. 46756. S. No. 26-549 T.)

QUANTITY: 3 devices at East Detroit, Mich.

SHIPPED: On an unknown date, from Germany.

LABEL IN PART: (All devices) "Nemectron" and (2 devices) "Deutsche Nemectron Gesellschaft m.b.h. * * * Lindau (B) Germany."

ACCOMPANYING LABELING: 2 wiring diagrams and 1 leaflet entitled "Nemectron The Apparatus for Bio-Electric Treatments."

RESULTS OF INVESTIGATION: The devices had been delivered for repair to East Detroit prior to 11-13-61, by Mrs. Beate Lisa Harter, t/a Harter's Clinic, Inc., Detroit, Mich. The device was understood to consist of an electrical apparatus which converted household current into stimulating voltages which were applied to the human body through four applicator pads.

LIBELED: 11-30-61, E. Dist. Mich.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling of the article contained false and misleading representations that the article was effective for toning the body; strengthening the body; regenerating the tissues; rejuvenating the body; producing beneficial effects on the cells and tissues of the body, including the nerves, muscles, glands, and brain; overcoming the damages and ravages of age; restoring the lost elasticity of the skin; removing deposits of fat (double chin), and obnoxious toxic substances caused by impaired cellular metabolism; removing wrinkles and furrows; improving cellular metabolism; accelerating venous and lymphatic circulation, thus overcoming cellulitis and acne; "normalizing" a condition of underdevelopment of the breasts and overdevelopment of the breasts; overcoming a condition of atonic abdominal muscles; strengthening the feet; eliminating edema and infiltration of the ankle and calf; and overcoming a condition of fallen arches.

DISPOSITION: 2-27-63. Beate Lisa Harter, Detroit, Mich., and Elva Nudi, Pittsburgh, Pa., having appeared as claimants and consented to the entry of a decree, judgment of condemnation was entered and the article was released under bond to be brought into compliance with the law.

7589. Comforette Leg Elevator. (F.D.C. No. 47182. S. No. 45-630 T.)

QUANTITY: 57 devices at East Peoria, Ill.

SHIPPED: 9-12-61, from Santa Ana, Calif., by Hill Manufacturing Co.

ACCOMPANYING LABELING: Leaflets reading in part "New Comforette Leg Elevator" and "For The Fastest, Most Comfortable And Complete Relaxation You've Ever Experienced."

RESULTS OF INVESTIGATION: The device appeared to be constructed of gold-colored tubular metal covered with colored plastic material and made in such fashion that it served as a support for the legs, elevating them approximately 10 inches when the user was resting in a supine position.

LIBELED: 3-19-62, S. Dist. Ill.

CHARGE: 502(a)—when shipped, the accompanying labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for heart conditions, and nervous tension, and that the article would restore energy and improve circulation.

DISPOSITION: 8-2-63. Consent—claimed by Kaufman's Furniture Co., East Peoria, Ill., and relabeled.

7590. Elastic abdominal support device. (F.D.C. No. 48598. S. No. 51-810 V.)

QUANTITY: 124 individually ctn'd. devices at Portland, Oreg.

SHIPPED: Between 9-4-62 and 10-30-62, from Los Angeles, Calif., by Strick of Hollywood.

LABEL IN PART: (Device) "Relax Cinch by Strick of Hollywood."

ACCOMPANYING LABELING: Leaflet entitled "Important! Read Before Wearing Relax-Cinch Health Belt."

RESULTS OF INVESTIGATION: Examination showed the article to be an elasticized abdominal belt in two sections, front and back, held together by $\frac{3}{4}$ -inch cotton straps and metal buckles, three on each side. The front section was 6 inches wide and had a $\frac{1}{4}$ -inch thick foam rubber pad, $4\frac{1}{2}$ inches wide, sewed to the inside at the middle. The back section varied in width from $5\frac{1}{2}$ inches at the sides to $7\frac{1}{2}$ inches at the center. The bottom of the back section was reinforced with another thickness of elasticized cotton.

LIBELED: 1-17-63, Dist. Oreg.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for giving one a mental and physical lift; relieving heart strain; relaxing the heart; protecting against many ailments by correcting sagging abdominal organs and faulty posture; and improving blood circulation.

DISPOSITION: 2-11-63. Consent—claimed by Strick of Hollywood, Los Angeles, Calif., for relabeling.

7591. Oxygen inhalers. (F.D.C. No. 48815. S. No. 8-273 V.)

QUANTITY: 138 devices, and 286 pkgs., each containing 3 refill cartridges, at Boston, Mass., in possession of Joseph Breck & Sons Corp.

SHIPPED: 1-28-63 and 3-5-63, from New York, N.Y., by Val-U-Air Products, Inc.

LABEL IN PART: (Ctn.) "Oxygen Air-Aid Oxygen Inhaler & Cartridge Now available to everyone * * * Endorsed & Supported by Leading Professionals! Warning * * * highly inflammable * * * oxygen content: 3 liters U.S.P. Val-U-Air Products Inc., New York N.Y.," (device) "Air-Aid * * * Caution," and (pkgs.) "Caution: Keep away from heat and oil U.S.P. Oxygen."

ACCOMPANYING LABELING: Leaflets entitled "Follow these simple steps to use your Air-Aid Oxygen Inhaler" and "Now! Health giving . . . life giving . . . lift giving Oxygen * * * Air-Aid Pocket-size, refillable oxygen inhaler"; and sales catalogs entitled "Sale 146th Anniversary Breck's of Boston."

LIBELED: 3-20-63, Dist. Mass.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for coronary breathlessness, angina pains, overindulgence, athletic exhaustion, croup, and asthma; and that the article contained life-giving capabilities.

DISPOSITION: 4-30-63. Consent—claimed by Joseph Breck & Sons, Inc., and relabeled.

7592. Electrion air purifier. (F.D.C. No. 49069. S. No. 8-230 V.)

QUANTITY: 4 devices at Needham, Mass.

SHIPPED: 3-15-63, from Providence, R.I., by Skam, Inc.

LABEL IN PART: "Electrion Manufactured by Skam Inc. Providence 3, R.I."

ACCOMPANYING LABELING: Leaflets entitled "The Magic of Negative Ions," "This Veterinarian Was Sceptical," "If Cats Could Talk," and "Grayarlin Kennels * * * are controlling communicable animal diseases."

RESULTS OF INVESTIGATION: The article appeared to be a negative ion generator housed in a metal cabinet containing a mercury vapor lamp, transformer, fan, motor and pilot light.

LIBELED: 6-7-63, Dist. Mass.

CHARGE: 502(a)—when shipped, the accompanying labeling of the article contained false and misleading representations that the article was an air purifier and germicidal; was adequate and effective for invigorating and improving the health, efficiency, and alertness of man; revitalizing animals and improving their health and disposition; and for the prevention and control of airborne infections and communicable animal diseases.

DISPOSITION: 9-30-63. Default—destruction.

7593. Air purifiers. (F.D.C. No. 48810. S. No. 21-091 V.)

QUANTITY: 15 devices at Salt Lake City, Utah.

SHIPPED: 11-6-62 and 12-12-62, from Wooster, Ohio, by Aranair Corp.

LABEL IN PART: (7 devices) "Aranair Electrical Air Purifier Model MR Serial 4001 (or other numbers) * * * Aranair Corporation Wooster, Ohio"; (8 devices) "Homozone Electrical Air Purifier Model AS [or "GS-6"] * * * Mfd. only by Aranair Corporation Wooster, Ohio."

ACCOMPANYING LABELING: Leaflets entitled "You Can't Smell That Odor, But Your Customer Can!"; and looseleaf notebooks, containing testimonials, magazine and newspaper article reprints, and miscellaneous material, as follows: "Chapter XXIV Air Conditioning of Large Garages"; Aranair Provides what Scientific Tests Prove to be Needed for Better, Healthful Living"; "Warning Given on Chlorophyll"; "How is Ozone (O₃) Generated? How does Ozone Control Odor, Mold, Mildew, and Bacteria?" "A Homozone Price List"; Testimonials from Apple Creek State Hospital, Apple Creek, Ohio, dated Sept. 29, 1963 and October 5, 1963; Testimonial from Hall Dodds Company, Detroit, Michigan, dated March 22, 1949; Testimonial from Mrs. Evelyn E. Jordan, Portsmouth, Ohio, dated October 6, 1958; Testimonial from George I. Petit, Inc., Doylestown, Ohio, dated February 7, 1958; Testimonial from E. R. Gertner and Company, Inc., Orlando, Florida, dated Jan. 13, 1960; "Reprint from Refrigerating Engineering-Sept. 1939"—"Maintaining Fresh Air Indoors with Nature's Air Purifier."

RESULTS OF INVESTIGATION: Each device appeared to be a metal box containing a fan, air filter, transformer and a mica plate condenser for the production of ozone.

LIBELED: 3-19-63, Dist. Utah.

CHARGE: 502(a)—when shipped, the accompanying labeling of the articles contained false and misleading representations that the articles were adequate and effective as a treatment for and preventive of carbon monoxide poisoning, angina, breathing difficulties, sinus, sore throat, grippe, pneumonia, and influenza; that use of the articles reduced airborne infections; created healthful living conditions; and that ozone is absolutely harmless.

DISPOSITION: 6-25-63. Consent—claimed by Aranair Corp. and released under bond for relabeling.

7594. Dustronic air purifier. (F.D.C. No. 48066. S. No. 15-874 T.)

QUANTITY: 4 devices at Cincinnati, Ohio, in possession of Dustronic Sales Co. of Cincinnati.

SHIPPED: Between 6-6-62 and 7-5-62, from Northbrook, Ill., by National Radex Sales Corp.

LABEL IN PART: "Dustronic."

ACCOMPANYING LABELING: Pamphlets entitled "Now dramatic relief * * * Dustronic" and circulars entitled "A Reader's Digest Reprint, Ions Can Do Strange Things To You."

RESULTS OF INVESTIGATION: The device was a metal cabinet containing a charcoal filter, aluminum mesh filter, circulating fan, ionizing wires, and 8 louvered aluminum collector plates.

LIBELED: 8-28-62, S. Dist. Ohio.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the device would provide relief from asthma, airborne allergies, hay fever, sneezing, wheezing, and coughing; provide a new lease on life for hay fever and other airborne-allergy sufferers; relieve airborne-irritant illnesses; remove contaminants blamed for over 85 percent of all respiratory problems; make body-racking sneezes, wheezes, and weepy eyes a thing of the past; eliminate the bacilli and viral causes of tubercle, meningitis, and pneumonia; relieve itching noses; reduce or eliminate pain; make burns dry out faster, heal faster, with less scarring, and that it would reduce the need for skin grafting; and promote better sleep.

DISPOSITION: 10-3-63. Default—1 device and 1 copy of each of the labeling delivered to the Food and Drug Administration; remainder destroyed.

7595. Electro Hygiene vacuum cleaner device and sanitizing crystals. (F.D.C. No. 47701. S. Nos. 17-839 T, 58-319 T.)

QUANTITY: 12 devices and 75 jars of crystals, at Indianapolis, Ind., in possession of Electro Hygiene Sales Corp.

SHIPPED: The devices were shipped between 1-22-62 and 5-2-62, from Cleveland, Ohio, by P. A. Geier Co.; and the crystals were shipped on 2-21-62, from Erlanger, Ky.

LABEL IN PART: (Device) "Electro Deluxe Hygiene" and "Model 966 * * * The P. A. Geier Co., Cleveland, Ohio"; and (jar) "Sanitizing Crystalline Preparation A Specially prepared for use in the Hygiene * * * Active Ingredient (Formaldehyde Gas) 0.4% Inert Ingredient (Paradichlorobenzine Crystal) 99.6% Instructions: * * * tests show that these crystals, when used as directed * * * reduce the number of some bacteria commonly found in the dust bag of vacuum cleaners."

ACCOMPANYING LABELING: Booklets entitled "Facts and Tests on Electric Hygiene," "Electro Hygiene Demonstration and Sales Manual," "Instructions For Its Care and Operation," and "For a Healthier, Happier Home."

RESULTS OF INVESTIGATION: Some of the booklets had been shipped by a Dayton, Ohio firm or received by the dealer at sales meetings held periodically by the Dayton, Ohio firm, and the other booklets had been shipped by P. A. Geier Co., Cleveland, Ohio.

Examination indicated the device to be of similar design to the conventional tank-type vacuum cleaner, with the usual cleaning attachments. The crystals were intended to be inserted into a special chamber of the device. Statements in the accompanying labeling attributed various benefits to the use of the device with the crystals.

LIBELED: 7-12-62, S. Dist. Ind.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling contained false and misleading representations that the articles were adequate and effective as a treatment for relieving asthma, hay fever, sinus, common colds, and bronchitis; guarding against pneumonia, tuberculosis, intestinal disturbances, influenza, whooping cough, polio, measles, and scarlet fever; improving health through germ destruction; ridding the air of all organic life; to annihilate germ-laden dirt and dust from all parts of the home; to serve as a safeguard to children's health; and to banish influence of germs in the home; and 502(b) (1)—when shipped, the label of the crystals failed to bear the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: 5-14-63. Default—destruction of 50 jars of the crystals and delivery of the remaining jars of crystals and the one device actually seized, to the Food and Drug Administration.

DRUG FOR VETERINARY USE*

7596. Centex Broiler Starter. (F.D.C. No. 48777. S. No. 60-869 V.)

QUANTITY: 3,000 lbs. at Logansport, La.

SHIPPED: 2-26-63 and 4-4-63, from Center, Tex., by Rite-Care Corp.

LABEL IN PART: "Identification Centex Broiler Starter Medicated * * * 3,5 Dinitrobenzamide 0.025 percent * * * Ingredients * * * Manufactured Rite-Care Corp., Center, Texas, feed instructions."

RESULTS OF INVESTIGATION: Analysis showed that the article contained no 3,5-dinitrobenzamide and that it contained approximately 0.0130 percent of amprolium.

LIBELED: 5-16-63, W. Dist. La.

CHARGE: 502(a)—when shipped, the label statement "3,5-Dinitrobenzamide 0.025 percent" was false and misleading; and 502(e) (2)—the article failed to bear a label containing the common or usual name of the active drug ingredient, amprolium.

DISPOSITION: 6-26-63. Default—destruction.

**DRUGS ACTIONABLE BECAUSE OF AN IMITATION OF AND SALE
UNDER NAME OF ANOTHER DRUG****

7597. Imitation Meticorten tablets, Hydrodiuril tablets, and Equanil tablets. (F.D.C. No. 45688. S. Nos. 13-547 R, 13-549/50 R.)

INFORMATION FILED: 7-26-61, N. Dist. Ill., against Berwyn Lawndale Medical Supply, Inc., Berwyn, Ill.

SHIPPED: Between 10-14-60 and 10-17-60, while quantities of imitation tablets of Meticorten, Hydrodiuril, and Equanil were being held for sale after shipment in interstate commerce, the defendant caused such tablets to be offered for sale and sold, which act resulted in such tablets being misbranded.

CHARGE: 502(i) (2)—the articles were imitations of other drugs, namely, Meticorten, Hydrodiuril, and Equanil; and 502(i) (3)—the articles were offered for sale under the names of other drugs, namely, Meticorten, Hydrodiuril, and Equanil.

PLEA: Guilty.

DISPOSITION: 2-15-62. \$600 fine.

7598. Imitation Hydrodiuril tablets. (F.D.C. No. 47842. S. No. 58-455 R.)

INFORMATION FILED: 8-21-62, N. Dist. Ill., against Lazar Drugs, Inc., Chicago, Ill., and Bernard S. Lazar, president.

ALLEGED VIOLATIONS: On 2-1-61, while hydrochlorothiazide tablets were being held for sale by the defendants after shipment in interstate commerce, the defendants offered for sale and sold hydrochlorothiazide tablets that were represented to be Hydrodiuril tablets, whereas the drug was not Hydrodiuril, but was an imitation.

*See also Nos. 7549, 7578, 7579.

**See also Nos. 7552-7554, 7570.

CHARGE: 502(i) (2)—the article was an imitation of another drug, Hydrodiuril; and 502(i) (3)—the article was offered for sale under the name of another drug, namely, Hydrodiuril.

PLEA: Corporation—guilty; individual—nolo contendere.

DISPOSITION: 10-11-62. Corporation—\$100 fine; individual—\$50 fine, plus costs.

DRUG ACTIONABLE BECAUSE OF FAILURE TO BEAR A LABEL CONTAINING AN ACCURATE STATEMENT OF THE QUANTITY OF CONTENTS*

7599. Paregoric. (F.D.C. No. 48766. S. No. 80-280 V.)

QUANTITY: 1,150 btl. at Cleveland, Ohio.

SHIPPED: 4-3-61 and 3-4-63, from Allegan, Mich., by L. Perrigo Co.

LABEL IN PART: (Btl.) "Gray's U.S.P. Paregoric (Tincture Opium camphorated) a mild anodyne and intestinal sedative each teaspoonful (5 cc.) contains 22 mg. opium Warning * * * one fluid ounce distributed by Gray Drug Stores, Inc., Cleveland, Ohio."

RESULTS OF INVESTIGATION: Examination showed the article to be approximately 3½ percent short volume.

LIBELED: 5-14-63, N. Dist. Ohio.

CHARGE: 502(b) (2)—when shipped, the article failed to bear a label containing an accurate statement of the quantity of contents, since the label statement "one fluid ounce" was inaccurate.

DISPOSITION: 6-11-63. Default—destruction.

DRUG ACTIONABLE BECAUSE OF FAILURE TO BEAR A LABEL CONTAINING THE NAME AND PLACE OF BUSINESS OF THE MANUFACTURER, PACKER, OR DISTRIBUTOR**

7600. Dextro-amphetamine sulfate tablets. (F.D.C. No. 47382. S. No. 56-597 T.)

QUANTITY: 12 1,000-tablet btl. at Amarillo, Tex.

SHIPPED: 1-10-62, from Altus, Okla., by Illinois California Express, Hill-Miller Div.

LABEL IN PART: (Btl.) "Dextro Amphetamine Sulfate Each Tablet Contains: 5 mg. of Dextro Amphetamine Sulfate Caution: Federal law prohibits * * * Distributed by" and (ctn.) "Handle with Care Glass From Van Dyke Pharmacal W. L. Palmer * * * Houston, Texas."

LIBELED: On or about 3-29-62, N. Dist. Tex.

CHARGE: 502(b) (1)—when shipped, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: 7-16-62. Default—destruction.

*See also Nos. 7541, 7556, 7557, 7539, 7560.

**See also Nos. 7541-7543, 7556-7559, 7561, 7566, 7595.

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¹ (7541, 7565, 7586, 7587) Injunction issued.² (7582) Seizure contested. Contains decision of the court.³ (7541) Injunction issued; contempt of preliminary injunction; contempt of permanent injunction contested; violation of probation.⁴ (7581) Seizure contested. Contains opinion of the court.

	N.J. No.		N.J. No.
Koch Treatment-----	^{1,3} 7541	Revitorgan Dilutionen Nr. 26 and Nr. 36-----	7544
Koch's Glyoxylide-----	^{1,3} 7541	Rheumatism, remedy for (de- vice) -----	¹ 7587
Labcatal-----	7544	Rojelan royal jelly capsules-----	7585
Leg Elevator, Comforette-----	7589	Royal jelly capsules, Rojelan-----	7585
Lumbago, remedy for. <i>See</i> Rheu- matism, remedy for.		Sciatica, remedy for. <i>See</i> Rheu- matism, remedy for.	
Mattress, Massaging, Pulse-A- Rhythm-----	¹ 7587	Secobarbital sodium capsules-----	7553, 7555
Metandren Linguets-----	7553	Seconal Sodium capsules-----	7554
Meticorten tablets, imitation-----	7597	Serpasil tablets-----	7554
Micro-Dynameter devices-----	7567, 7568	imitation-----	7554
Miltown tablets, imitation-----	7553	Skin disorders, remedy for-----	7584
Nemectron devices-----	7588	rejuvenating preparations-----	7563, 7564
Neuralgia, remedy for. <i>See</i> Rheumatism, remedy for		Slim-Mint chewing gum-----	⁴ 7581
Neuritis, remedy for. <i>See</i> Rheu- matism, remedy for.		Sta-Free deodorant-antiperspi- rant -----	7563
Neurobasal capsules-----	7547	Stemutrolin Lyophilized-----	7571
Neurolinometer devices-----	7566	Stomach disorders, remedy for-----	7584
Neygeront Dilutionen Nr. 64-----	7544	Streptomycin sulfate-----	7548
Neynormin Dilutionen Nr. 65-----	7544	Super-Amino tablets-----	7583
Nutra-Glo food supplement-----	² 7582	Tinc Zoin benzoin compound aer- osol -----	7584
Obesity, remedy for. <i>See</i> Reduc- ing preparation.		Toddlers vitamin and mineral supplement-----	² 7582
Oxygen inhalers-----	7591	Tonic, hair-----	7562
Paregoric-----	7599	Turkey grower medicated-----	7578
Penicillin-----	7548	Vacuum cleaner device, Electro Hygiene, and sanitizing crys- tals -----	7595
tablets-----	7552	Veterinary preparations-----	7549- 7551, 7578, 7579, 7596
Phenobarbital tablets-----	7552	(device)-----	7592
Pituitary, anterior tablets-----	7559	Vita 50 capsules-----	7584
Prescription drugs-----	7542, 7543	Vita-Glo food supplement-----	² 7582
and nonprescription drugs-----	7558	Vitamin C "400" tablets-----	7583
Prophylactics, rubber-----	7574-7577	Vitamin preparation-----	7583
Pulse-A-Rythm Massaging Mat- tress -----	¹ 7587	ViViBx Formula Nos. 190, 160, 152-A, and 80-A-----	7585
Pyralgin liquid and tablets-----	7560	Yeast tablets, brewer's-----	² 7582
Radioclast Model 40-----	¹ 7565	Young Again cosmetic cream---	7564
Reducing preparation-----	⁴ 7581		
Rejuvenator-----	7585		
Research Model devices-----	7566		
Respiratory conditions, remedies for (device)-----	7594, 7595		

¹ (7541, 7565, 7586, 7587) Injunction issued.² (7582) Seizure contested. Contains decision of the court.³ (7541) Injunction issued; contempt of preliminary injunction; contempt of permanent injunction contested; violation of probation.⁴ (7581) Seizure contested. Contains opinion of the court.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

	N.J. No.		N.J. No.
Aerosol Corp. of the South :		Cook, D. B. :	
Tinc Zoin benzoin compound		carrot, celery root, and beet	
aerosol-----	7584	juices-----	7580
Allied Mills, Inc. :		Cook's Finer Food. <i>See</i> Cook,	
turkey grower medicated-----	7578	D.B.	
Aranair Corp. :		Dean Rubber Manufacturing Co. :	
air purifiers-----	7593	rubber prophylactics-----	7577
Austin, Margaret :		Delta Pharmaceuticals, Inc. :	
Pulse-A-Rythm Massaging Mat-		Atoxin-----	7545
tress-----	¹ 7587	Dumas Milner Corp. <i>See</i> Taylor	
Berwyn Lawndale Medical Sup-		Laboratories.	
ply, Inc. :		Dustronic Sales Co. of Cincin-	
imitation Meticorten tablets,		nati :	
Hydrodiuril tablets, and		Dustronic air purifier-----	7594
Equanil tablets-----	7597	Ehrenreich, J. J. :	
Blake, H. L., Co., Inc. :		Dexedrine Sulfate tablets, dex-	
rubber prophylactics-----	7574	tro-amphetamine sulfate tab-	
Breck, Joseph, & Sons Corp. :		lets, secobarbital sodium	
oxygen inhalers-----	7591	capsules, and imitation	
Burroughs, S. A. :		Chloromycetin capsules-----	7555
color-lamp components-----	¹ 7586	Electro Hygiene Sales Corp. :	
Burroughville Specialties :		Electro Hygiene vacuum clean-	
color-lamp components-----	¹ 7586	er device and sanitizing	
Cabot Pharmaceuticals, Inc. :		crystals-----	7595
timed disintegration tablets		Ellis Research Laboratories,	
and capsules-----	7546	Inc. :	
Cahan, M. D. :		Micro-Dynameter devices--	7567, 7568
Dexedrine Sulfate tablets, dex-		Foundation For The Advance-	
tro-amphetamine sulfate tab-		ment of Chiropractic Re-	
lets, secobarbital sodium		search, Inc. :	
capsules, and imitation Chloro-		Neurolinometer devices and Re-	
mycetin capsules-----	7555	search Model devices-----	7566
Century Foods Co. :		Geir, P. A., Co. :	
vitamin and mineral supple-		Electro Hygiene vacuum clean-	
ments, brewer's yeast tablets,		er device-----	7595
and dehydrated cabbage tab-		Gray Drug Stores, Inc. :	
lets-----	7582	paregoric-----	7599
Century Laboratories :		Guastello, George :	
vitamin and mineral supple-		various prescription drugs-----	7552
ments, brewer's yeast tab-		Harter, Mrs. B. L. :	
lets, and dehydrated cab-		Nemectron devices-----	7588
bage tablets-----	7582	Harter's Clinic, Inc. <i>See</i> Harter,	
Chesapeake Drug Store :		Mrs. B. L.	
various prescription and non-		Herrschnner, Frederick :	
prescription drugs-----	7558	various products containing	
		royal jelly, safflower oil, or	
		lecithin-----	7585

¹ (7541, 7565, 7586, 7587) Injunction issued.

	N.J. No.		N.J. No.
Hill Manufacturing Co.:		Lincoln Laboratories, Inc.:	
Comforette Leg Elevator.....	7589	Stemutrolin Lyophilized.....	7571
Hill-Miller Div. <i>See</i> Illinois		Lion Latex Corp.:	
California Express.		rubber prophylactics.....	7575
Illinois California Express, Hill-		M & M Rubber Co.:	
Miller Div.:		rubber prophylactics.....	7574-7576
dextro-amphetamine sulfate		Mayfield, Dr., Laboratories, Inc.:	
tablets.....	7600	Arvicin.....	7550
Institut Merieux:		McPherson Drug Co.:	
various injectable drugs.....	7544	various prescription drugs.....	7543
International Centre for Bio-		Mills Pharmaceuticals, Inc.:	
logical Research:		anterior pituitary tablets.....	7559
various injectable drugs.....	7544	National Radex Sales Corp.:	
International Electronics Re-		Dustronic air purifier.....	7594
search Society, Inc.:		Norment, D. M.:	
devices designated as "Elec-		imitation Serpasil tablets,	
tronic Magnetic Model G,"		Serpasil tablets, Diuril tab-	
"Electro Sine Galvanic		lets, and Seconal Sodium	
Model 200," "Radioclast		capsules.....	7554
Model 40," Auto Electronic		Northern Biochemical Corp.:	
Radioclast Model 20, Series		Antivi'Sol-S and Antivi'Sol-	
800," and "Electronic Analy-		P.....	7549
sis Instrument Model F".....	¹ 7565	Palmer, W. L.:	
K-V Pharmacal Co.:		dextro-amphetamine sulfate	
enzyme compound tablets.....	7584	tablets.....	7600
Kassik Companies:		Paris, Jeanean:	
Kassik's hog pellets.....	7579	Young Again cosmetic cream..	7564
King, C. G.:		Perrigo, L., Co.:	
imitation Dexedrine Sulfate		paregoric.....	7599
tablets and imitation Dex-		Pfizer, Chas., & Co., Inc.:	
amyl tablets.....	7570	streptomycin sulfate and peni-	
Kingston Laboratories, Ltd.:		cillin.....	7548
timed disintegration tablets		Philadelphia Laboratories, Inc.:	
and capsules.....	7546	caffeine timed disintegration	
Kolmar Laboratories, Inc.:		capsules.....	7569
Young Again cosmetic cream..	7564	Prospect Pharmacy:	
Laboratories Terrier, Inc.:		various prescription drugs....	7552
streptomycin sulfate and peni-		Publisher's Printing Co.:	
cillin.....	7548	Vitamin C "400" tablets and	
Lawrence Drug Co.:		Super-Amino tablets.....	7583
various prescription drugs....	7553	Pulsa-Tronics, Inc.:	
Lawrence, K. K.:		Pulse-A-Rythm Massaging Mat-	
various prescription drugs....	7553	tress.....	¹ 7587
Lazar, B. S.:		Pulsnation Enterprises, Inc.:	
imitation Hydrodiuril tablets..	7598	Pulse-A-Rythm Massaging Mat-	
Lazar Drugs, Inc.:		tress.....	¹ 7587
imitation Hydrodiuril tablets..	7598	Ransom, J. L., M.D.:	
Lewis, D. L.:		amphetamine phosphate tab-	
herb capsules.....	7557	lets.....	7556
		Regent Pharmacy. <i>See</i> King, C.	
		G.	

¹ (7541, 7565, 7586, 7587) Injunction issued.

	N.J. No.		N.J. No.
Reynolds Clinic. <i>See</i> Reynolds, M. G., R. G., and T. T. G.		Roby, L. L., Jr.:	
Reynolds, M. G.:		devices designated as "Elec-	
drug for injection represented		tronic Magnetic Model G,"	
by names of "Koch Treat-		"Electro Sine Galvanic	
ment," "Glyoxylide," and		Model 200," "Radioclast	
"Koch's Glyoxylide," and de-		Model 40," "Auto Electronic	
vice consisting of hypodermic		Radioclast Model 20, Series	
syringe and needle-----	1 7541	800," and "Electronic Analy-	
Reynolds, R. G.:		sis Instrument Model F"---	1 7565
drug for injection represented		Roby, L. L., Manufacturing	
by names of "Koch Treat-		Corp.:	
ment," "Glyoxylide," and		devices designated as "Elec-	
"Koch's Glyoxylide," and de-		tronic Magnetic Model G,"	
vice consisting of hypoder-		"Electro Sine Galvanic Model	
mic syringe and needle-----	1 7541	200," "Radioclast Model 40,"	
Reynolds, T. T. G.:		"Auto Electronic Radioclast	
drug for injection represented		Model 20, Series 800," and	
by names of "Koch Treat-		"Electronic Analysis Instru-	
ment," "Glyoxylide," and		ment Model F"-----	1 7565
"Koch's Glyoxylide," and de-		Rogatol Pharmaceutical Co.,	
vice consisting of hypodermic		Inc.:	
syringe and needle-----	3 7541	Diamicina and Neurobasal cap-	
Richardson-Merrell, Inc. <i>See</i>		sules-----	7547
Vick Chemical Co.		Rojelle Pharmacal Co.:	
Riley, J. R.:		Rojelan royal jelly capsules--	7585
Pulse-A-Rythm Massaging Mat-		Royal Products Co.:	
tress-----	1 7587	rubber prophylactics-----	7574
Rilling Dermetics, Inc., Div. of		Savage Laboratories, Inc.:	
Turner-Hall Corp.:		Pyrargin products-----	7560
cosmetic products-----	7563	Scott, D. J.:	
Rite-Care Corp.:		Pulse-A-Rythm Massaging	
Centex Broiler Starter-----	7596	Mattress -----	1 7587
Roby, L. L.:		Service Drug Store of De	
devices designated as "Elec-		Quincy, Inc.:	
tronic Magnetic Model G,"		imitation Serpasil tablets, Ser-	
"Electro Sine Galvanic Model		pasil tablets, Diuril tablets,	
200," "Radioclast Model 40,"		and Seconal Sodium cap-	
"Auto Electronic Radioclast		sules-----	7554
Model 20, Series 800," and		Service Rexall Drug Store, The.	
"Electronic Analysis Instru-		<i>See</i> Service Drug Store of	
ment Model F"-----	1 7565	De Quincy, Inc.	
		Skam, Inc.	
		Electrion air purifier-----	7592

¹ (7541, 7565, 7586, 7587) Injunction issued.

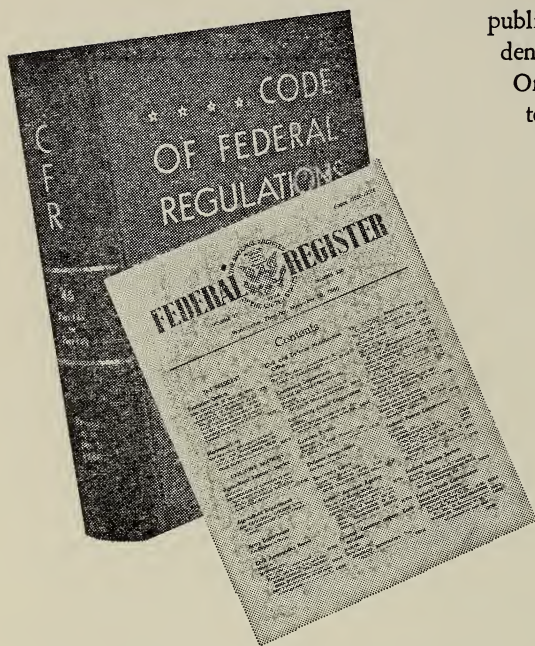
³ (7541) Injunction issued; contempt of preliminary injunction; contempt of permanent injunction contested; violation of probation.

	N.J. No.		N.J. No.
Spalitto, Peter :		Universal Nutritions, Inc. :	
various prescription drugs----	7552	Vitamin C "400" tablets and	
Spector, Leizer :		Super-Amino tablets-----	7583
Dexedrine Sulfate tablets, dex-		Val-U-Air Products, Inc. :	
tro-amphetamine sulfate tab-		oxygen inhalers-----	7591
lets, secobarbital sodium cap-		Van Dyke Pharmacal :	
sules, and imitation Chloro-		dextro-amphetamine sulfate	
mycetin capsules-----	7555	tablets-----	7600
Strick of Hollywood :		Vick Chemical Co., Div. of Rich-	
elastic abdominal support de-		ardson-Merrell, Inc. :	
vise-----	7590	cough drops-----	7561
Sure Shot Laboratories :		Walker, C. F. :	
hair tonic-----	7562	imitation Serpasil tablets, Ser-	
Taylor Laboratories, Div. of		pasil tablets, Diuril tablets,	
Dumas Milner Corp. :		and Seconal Sodium cap-	
enzyme compound tablets, Tinc		sules-----	7554
Zoin benzoin compound aéro-		Walnut Grove Products Co., Inc. :	
sol, and Vita 50 capsules---	7584	medicated feed-----	7551
Terrace Pharmacy Co., Inc. :		White's Comb Vendor, Inc. :	
various prescription drugs----	7542	rubber prophylactics-----	7574
Thompson Medical Co., Inc. :		Windsor Corp. :	
Slim-Mint chewing gum-----	⁴ 7581	caffeine timed disintegration	
Toftness Chiropactic Clinic :		capsules-----	7569
Neurolinometer devices and Re-		Windsor Pharmacy, Inc. :	
search Model devices-----	7566	Dexedrine Sulfate tablets, dex-	
Turner-Hall Corp. :		tro-amphetamine sulfate tab-	
cosmetic products-----	7563	lets, secobarbital sodium cap-	
See also Rilling Dermetics,		sules, and imitation Chloro-	
Inc.		mycetin capsules-----	7555

⁴ (7581) Seizure contested. Contains opinion of the court.

1997. The *Journal of the Royal Society of Medicine*, 1997, 90, 1-2.
1998. The *Journal of the Royal Society of Medicine*, 1998, 91, 1-2.
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2024. The *Journal of the Royal Society of Medicine*, 2024, 117, 1-2.
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U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

7601-7640

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were alleged to be adulterated or misbranded, or otherwise violative of the Act, when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent, and (2) a criminal proceeding which was terminated upon a plea of guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceeding is against the *individual* charged to be responsible for the violation.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., July 15, 1964.

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*For omission of, or unsatisfactory, ingredients statements, see Nos. 7610, 7622; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 7610, 7638; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 7610, 7638; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 7638; cosmetics under the drug provisions of the Act, Nos. 7617, 7638.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN ALLEGED VIOLATIONS REPORTED IN D.D.N.J. NOS. 7601-7640

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its quality and purity fell below the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from or its quality fell below, that which it purported or was represented to possess; and Section 501(d) (2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(c), a word, statement, or other information required by, or under authority of, the Act to appear on the label or labeling of the article was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient contained therein; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(1), the article was composed wholly or in part of a kind of penicillin, streptomycin, or bacitracin, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b) (4), the article was a drug subject to Section 503(b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application, or an approval of an application, filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUGS FOR HUMAN USE

7601. Liefcort. (F.D.C. No. 48477. S. No. 48-777 V.)

QUANTITY: 10 unlabeled btls. and 1 labeled btl. at Stockton, Calif.

SHIPPED: Prior to 11-28-62, from outside the State of California, by an unknown shipper.

LABEL IN PART: "Liefcort Adrenocortical Preparation Anabolic . . . Produced by Endocrine Research Laboratories, Beaurepaire, Que., Canada . . . Lot #107 15 CC. . . to be used by qualified investigators only."

RESULTS OF INVESTIGATION: Analysis of samples in other shipments of the article showed that the article contained prednisone and estradiol, or pred-

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FOOD AND DRUG ADMINISTRATION

NOV 1 5 1962

nisone, estradiol, and testosterone in quantities sufficient to be dangerous to health when used as directed, and that the article did not contain hydrocortisone.

LIBELED: 12-4-62, N. Dist. Calif.

CHARGE: 501(c)—when shipped, the quality and purity of the article fell below that which it purported or was represented to possess; 505(a)—the article was a new drug which may not be introduced into interstate commerce since no approval of an application filed pursuant to law was effective with respect to such drug, and it was not exempt from such requirement since it did not comply with the regulations applicable to drugs for investigational use.

DISPOSITION: 2-27-63. Default—destruction.

7602. Virac Rex solution. (F.D.C. No. 48710. S. No. 21-873 V.)

QUANTITY: 5 btls. at Watertown, N.Y.

SHIPPED: 1-30-63, from Portland, Oreg., by Ruson Laboratories, Inc.

LABEL IN PART: (Btl.) “. . . One U.S. Gallon for Hospital and Clinic Solution Rex Virac the Modern Iodine Broad Spectrum Microbicide, Ruson Laboratories, Inc., Portland 2, Oregon, Active Ingredients: Undecoylium Chloride-Iodine, 1.80 per cent (Available Elemental Iodine 0.6 per cent) . . .”

LIBELED: 2-21-63, N. Dist. N.Y.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce since no approval of an application filed pursuant to law was effective with respect to such drug.

DISPOSITION: 4-25-63. Default—destruction.

7603. Virac Rex solution. (F.D.C. No. 48234. S. Nos. 82-513/14 T.)

QUANTITY: 13 btls., at Tacoma, Wash., and 32 btls., at Seattle, Wash.

SHIPPED: Between 6-13-62 and 7-23-62, from Portland, Oreg.

LABEL IN PART: “One U.S. Gallon * * * Solution Rex Virac The Modern Iodine Broad Spectrum Microbicide * * * Ruson Laboratories, Inc. Portland 2, Oregon * * * Active Ingredients: Undecoylium Chloride Iodine 1.80% (Available elemental iodine-0.6%).”

ACCOMPANYING LABELING: Brochure entitled “a surgical antiseptic and therapeutic agent Virac-Modern Iodine * * * Detailed use and Dilution Recommendations.”

LIBELED: 10-22-62, W. Dist. Wash.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 2-12-63. Default—destruction.

7604. Virac Rex solution. (F.D.C. No. 48616. S. No. 4-206 V.)

QUANTITY: 8 ctns., 6 btls. each, at New Windsor, Md.

SHIPPED: 12-17-62, from Portland, Oreg., by Ruson Laboratories, Inc.

LABEL IN PART: (Btl.) “One U.S. Gallon For Hospital and Clinic Solution Rex Virac The Modern Iodine Broad Spectrum Microbicide * * * Ruson Laboratories, Inc. Portland 2, Oregon * * * Active Ingredients: Undecoylium Chloride-Iodine . . . 1.80% (Available elemental iodine-0.6%).”

LIBELED: 1-24-63, Dist. Md.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce since no approval of an application filed pursuant to 505 (b) was effective with respect to such drug.

DISPOSITION: 2-26-63. Default—destruction.

7605. Martrate-45 timed disintegration capsules and Martrate-45 with phenobarbital timed disintegration capsules. (F.D.C. No. 48387. S. Nos. 22-520/1 V.)

QUANTITY: 267 100-capsule btls. without phenobarbital, and 213 100-capsule btls. with phenobarbital, at Albuquerque, N. Mex.

SHIPPED: Between 11-30-61 and 2-23-62, from St. Louis, Mo., by Shaw Pharmaceutical Co.

LABEL IN PART: (Btl.) "100 Martrate-45 * * * Timed Disintegration Capsules Produced For Marsh-Emory Laboratories, Inc. Albuquerque, N. Mex. * * * Directions: * * * Caution: * * * Each capsule contains: Pentaerythritol Tetranitrate 45 mg.; (213-btl. lot additionally labeled in part) ["with Phenobarbital"]."

LIBELED: 11-29-62, Dist. N. Mex.

CHARGE: 505(a)—the articles were new drugs which may not be introduced into interstate commerce since no approval of an application filed pursuant to law was effective with respect to such drugs and the articles were not exempt from 505(a) since they did not comply with the regulations with respect to new drugs for investigational use.

DISPOSITION: 1-2-63. Default—destruction.

DRUG FOR VETERINARY USE

7606. Prescription No. T-193. (F.D.C. No. 48451. S. No. 33-601 V.)

QUANTITY: 5 drums at Richland Center, Wis.

SHIPPED: On an unknown date and 8-28-62, from Charles City, Iowa, by Dr. Mayfield Laboratories.

LABEL IN PART: "5 No. O. J. Mayfield, D.V.M. Charles City, Iowa Prescription No. T-193 for lowering blood pressure in turkeys."

RESULTS OF INVESTIGATION: Analysis showed that the article contained reserpine.

LIBELED: 11-16-62, W. Dist. Wis.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce since no approval of an application filed pursuant to law was effective with respect to such drug.

DISPOSITION: 2-25-63. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE FOR WHICH NONE HAD BEEN ISSUED

DRUGS FOR HUMAN USE

7607. Alphabiotic ointment. (F.D.C. No. 48626. S. No. 48-779 V.)

QUANTITY: 139 1-oz. tubes, at Modesto, Calif., in possession of Alpha Pharmaceuticals, Inc.

SHIPPED: The ingredients were shipped between 3-15-61 and 4-9-62, from New York, N.Y.

LABEL IN PART: "Alphabiotic Ointment Each gram contains: Polymyxin B Sulfate 5000 Units Bacitracin Zinc 400 Units Neomycin Sulfate 5 Mg. * * * Directions * * * Caution * * * Exp. Date Mar. 1964 Distributed by Alpha Pharmaceuticals, Inc., Modesto, California."

RESULTS OF INVESTIGATION: The article was manufactured in the State of California for the dealer from active ingredients shipped in interstate commerce.

Analysis showed that the article contained approximately 0.7 percent bacitracin, 4.6 percent polymyxin, and 3.5 percent neomycin of the declared amounts of these ingredients.

LIBELED: 2-5-63, N. Dist. Calif.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; 502(a)—the label statements "Polymyxin B Sulfate 5000 units"; "Bacitracin Zinc 400 Units"; and "Neomycin Sulfate 5 Mg." were false and misleading; and 502(1)—the drug was composed in part of a kind of bacitracin and was not from a batch with respect to which a certificate or release had been issued pursuant to 507.

DISPOSITION: 6-12-63. Default—destruction.

7608. Pectase. (F.D.C. No. 48693. S. Nos. 39-956/7 V.)

QUANTITY: 26 ctns., each containing 12 3-oz. btl., and 8 ctns., each containing 50 1-oz. btl., at Hato Rey, P.R.

SHIPPED: 9-20-62 and 10-20-62, from Hialeah, Fla., by Delta Pharmaceuticals, Inc.

LABEL IN PART: (Btl.) "Pectase Each Tablespoonful (15 cc.) contains neomycin sulfate 100 mg. (1.5 Gr.) (Equivalent to 70 Mg. Neomycin Base) Dihydrostreptomycin 150 mg. (2.3 gr.) * * * Caution * * * Delta Pharmaceuticals, Inc. Miami, Florida."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 67.7 percent (3-oz. btl.) and 65.5 percent (1-oz. btl.) of the labeled amount of neomycin.

LIBELED: 2-12-63, Dist. P.R.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; 502(a)—the label statements "Each Tablespoonful (15 cc.) contains neomycin sulfate 100 mg. (1.5 Gr.)" were false and misleading; and 502(1)—the drug was composed in part of a kind of streptomycin and was not from a batch with respect to which a certificate or release had been issued pursuant to 507.

DISPOSITION: 8-12-63. Default—destruction.

DRUG FOR VETERINARY USE

7609. Masti-Kure Hydro-Cort. (F.D.C. No. 47628. S. Nos. 7-395 T, 61-727 T.)

QUANTITY: 30 ctns., each containing 12 syringes, at Lawrence, Mass.

SHIPPED: 8-15-61, from North Franklin, Conn.

LABEL IN PART: (Syringe) "Masti-Kure Hydro-Cort * * * Each 15 cc. Syringe Contains: 100,000 Units Crystalline Penicillin; 250 mg. Dihydrostreptomycin base (as Sulfate); 20 mg. Hydrocortisone; 50 mg. Neomycin base (as Sulfate); 500 mg. Sulfathiazole; 500 mg. Sulfanilamide; 50 mg. Chlorobutanol; 10 mg. Cobalt Sulfate. Warning * * * Use As Directed on Circular * * * Lot #HC-26 Exp. Date Feb. 1963 (or July '63)."

RESULTS OF INVESTIGATION: Analysis showed that the article contained significantly less than the declared potency of penicillin.

LIBELED: 6-4-62, Dist. Mass.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; 502(a)—the label statement "Each 15 cc. Syringe Contains: 100,000 Units Crystalline Penicillin" was false and misleading, as applied to the product which contained less than the declared amount of penicillin; and 502(1)—the article was composed in part of penicillin and was not from a batch with respect to which a certificate or release had been issued pursuant to 507 and it was not exempt from that requirement.

DISPOSITION: 10-15-62. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

7610. Various drugs. (F.D.C. No. 48445. S. Nos. 61-801/900 V, 61-961/89 V.)

QUANTITY: 27 drums, ctns., or boxes, of various prescription and nonprescription drugs, at Dallas, Tex.

SHIPPED: 11-26-62, from Bountiful, Utah, by Mrs. Mildred Cates.

LIBELED: On or about 1-24-63, N. Dist. Tex.

CHARGE: 502(a)—when shipped, the words "Professional Sample," "Physician's Sample," and similar wording on the labels of a number of the articles were false and misleading as applied to articles intended for sale and not then intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)(1)—a number of the articles failed to bear the label containing the name and place of business of the manufacturer, packer, or distributor; 502(b)(2)—a number of the articles failed to bear a label containing an accurate statement of the quantity of contents; 502(e)(1)—the labels of a number of the articles failed to bear the common or usual name of the articles; 502(e)(2)—a number of the articles were fabricated from two or more ingredients and their labels failed to bear the common or usual name of each active ingredient; 502(f)(1)—the labeling of a number of the prescription drugs failed to bear adequate directions for use, and such articles were not exempt from such requirement since the articles were prescription drugs in the possession of a person who was not regularly and lawfully engaged in the distribution or dispensing of prescription drugs; 502(f)(1)—the labeling of a number of the nonprescription drugs failed to bear adequate directions for use for the purposes and conditions for which they were intended; and 503(b)(4)—a number of the drugs were subject to 503(b)(1), and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 3-11-63. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS AND DEVICES FOR HUMAN USE*

7611. Amphetamine tablets. (F.D.C. No. 49041. S. No. 46-908 X.)

QUANTITY: 100,000 tablets at Fort Smith, Ark., in possession of Chris Barros, M.D.

*See also No. 7610.

SHIPPED: Prior to 8-6-63, from outside the State of Arkansas, by an unknown shipper.

LIBELED: 8-6-63, W. Dist. Ark.

CHARGE: 502(f) (1)—when shipped, the label of the article failed to bear adequate directions for use, and it was not exempt from such requirement since it was a prescription drug which would not be used nor dispensed by the practitioner in the course of his professional practice upon prescription.

DISPOSITION: 9-11-63. Default—portion of the article delivered to the Food and Drug Administration and remainder destroyed.

7612. Amphetamine sulfate tablets. (F.D.C. Nos. 48593/4. S. Nos. 59-962 T, 59-964 T, 37-115/17 V.)

QUANTITY: 45,000 tablets at Birmingham, Ala., in possession of Pearce S. Johnson, M.D.

SHIPPED: Prior to 12-3-62, from outside the State of Alabama.

LIBELED: 11-30-62, N. Dist. Ala.; amended libel 12-3-62.

CHARGE: 502(f) (1)—while held for sale, the labeling of the article failed to bear adequate directions for use, and the article was not exempt from that requirement, since it was a prescription drug which was not and would not be used nor dispensed by the practitioner in the course of his professional practice.

DISPOSITION: 1-10-63. Default—a representative sample of approximately 2,300 tablets was delivered to the Food and Drug Administration, and the remainder of the tablets were destroyed.

7613. Amphetamine tablets and capsules. (F.D.C. No. 48421. S. No. 15-316 V.)

QUANTITY: 853,750 amphetamine tablets and capsules, at Nashville, Tenn., in possession of John A. McGee.

SHIPPED: Prior to 11-30-62, from outside the State of Tennessee.

LIBELED: 11-30-62, M. Dist. Tenn.

CHARGE: 502(f) (1)—while held for sale, the labeling of the article failed to bear adequate directions for use, and it was not exempt from such requirement.

DISPOSITION: 1-7-63. Default—portion delivered to the Food and Drug Administration and remainder destroyed.

7614. And-Est injection. (F.D.C. No. 49073. S. Nos. 33-993 V, 93-950 V.)

QUANTITY: 148 boxes, each containing 6 individually cntd. 10-cc. vials, at Minneapolis, Minn., in possession of Ulmer Pharmacal Co.

SHIPPED: 7-27-62 and 1-25-63, from Detroit, Mich.

LABEL IN PART: (Vial and ctn.) "And-Est For Intramuscular Injection * * * Each cc. contains: Crystalline Estrone U.S.P. 2 mg.; Crystalline Testosterone U.S.P. 25 mg.; * * * Dosage 1 cc. once or twice weekly * * * Caution * * * see package insert Distributed by The Ulmer Pharmacal Company, Minneapolis 3 Minnesota."

ACCOMPANYING LABELING: Package insert entitled "And-Est * * * Androgen-Estrogen Therapy."

RESULTS OF INVESTIGATION: The article had been shipped in bulk lots and subsequently repacked by the dealer into the cartons described above, at which time the package inserts were added.

LIBELED: 6-12-63, Dist. Minn.

CHARGE: 502(f) (1)—while held for sale, the labeling of the article failed to bear adequate directions for use and it was not exempt from such requirement, since its labeling failed to comply with the conditions prescribed by regulations.

DISPOSITION: 7-8-63. Consent—claimed by Ulmer Pharmacal Co., Minneapolis, Minn., for relabeling.

7615. Liver, iron, and vitamin injection. (F.D.C. No. 48791. S. No. 80-202 V.)

QUANTITY: 70 30-cc. vials at Cleveland, Ohio.

SHIPPED: 2-8-63, from Detroit, Mich., by Barry Laboratories, Inc.

LABEL IN PART: (Vial) "30 cc. size—Liver-Iron-Vitamins—Each 2 cc. containing 0.1 cc. Liver Injection, 10 mcgm. U.S.P., Peptonized Iron, 59 mg.; Niacinamide, 50 mg.; Pyridoxine Hydrochloride, 0.3 mg., Sodium Citrate, 1% Procaine Hydrochloride 1%—Mfg'd for J. D. Hacker Co. Cleveland 6, Ohio."

ACCOMPANYING LABELING: A package insert entitled, in part, "Liver-Iron-Vitamins Composition: * * * Action and Uses."

LIBELED: 5-28-63, N. Dist. Ohio.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the treatment of all types of anemia which respond to liver and iron salts; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use for the treatment of all anemias which respond to liver and iron salts for which the article was intended, prescribed, and recommended in its labeling.

DISPOSITION: 6-24-63. Default—destruction.

7616. Acnotabs tablets. (F.D.C. No. 47610. S. No. 56-221 T.)

QUANTITY: 179 ctns., each containing about 24,000 tablets, at Yonkers, N.Y.

SHIPPED: 3-29-62, from Cleveland, Ohio, by Strong, Cobb, Arner, Inc.

LABEL IN PART: (Ctn.) "Strong Cobb Arner, Inc. * * * Cleveland, Ohio Manufactured for Pannett Products SC Pink Tablets Formula No. Rx 185,550 C.D.O.C. Lot No. 7360-4 * * * 24,000 Tablets Formula containing at time of manufacture: Pancreatin Bile Salts Pepsin Vitamins A & C."

LIBELED: 5-29-62, S. Dist. N.Y.

CHARGE: 502(f) (1)—when shipped, the labeling failed to bear adequate directions for use.

DISPOSITION: 4-2-63. Consent—claimed by Pannett Products, Inc., New York, N.Y., and ordered released under bond for relabeling after approval of the new labeling by the Food and Drug Administration.

7617. Coty Dermacare. (F.D.C. No. 48739. S. No. 45-689 V.)

QUANTITY: 2,174 4-oz. btls. at Memphis, Tenn.

SHIPPED: 8-5-60, from New York, N.Y., by Coty, Inc.

LABEL IN PART: "Coty Medicated Foam Wash Dermacare For Pimples, Acne, Blackheads * * * No. 460 Active Ingredients * * * Pharmaceutical Division of Coty Research Laboratories, Coty, Inc., New York."

LIBELED: 4-5-63, W. Dist. Tenn.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for pimples, acne, and blackheads; and 502(f) (1)—the labeling failed to bear dietary instructions and instructions to use a keratolytic agent

with the article in order that it be effective in the treatment of acne pimples.
DISPOSITION: 5-6-63. Default—destruction.

7618. Micro-Dynameter devices (3 seizure actions). (F.D.C. Nos. 47720, 47830, 47942. S. Nos. 5-655/6 T; 38-912 T; 71-226 T.)

QUANTITY: 4 devices, at Denton, Md., Montgomery, Ala., and Big Spring, Tex.

SHIPPED: Between 1-1-57 and 7-15-62, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "For Scientific Body Analysis The Ellis Micro-Dynameter Mfd. by Ellis Research Laboratories, Inc., Chicago."

RESULTS OF INVESTIGATION: Examination indicated that the devices were essentially galvanometers for measuring electrical currents and electrical potentials of small magnitude. Each device was mounted in a metal cabinet, on the face of which was a scale or meter intended to measure the flow of current in milliamperes, together with a number of dials which could be set at numbered or lettered positions. The dial settings were intended to increase or decrease the resistance of the current flowing through the device. The current which flowed and was measured by the scale or meter was generated by closing the circuit between two dissimilar metal "probes." The circuit was closed by placing the "probes" at different points on the human body, by placing the "probes" together, or by immersing them in water.

ACCOMPANYING LABELING: Various pieces of literature pertaining to the device.

LIBELED: 7-10-62, Dist. Md.; 8-17-62, Dist. Ala.; and 8-31-62, N. Dist. Tex.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for diagnosing disease; and 502(f) (1)—the labeling of the articles failed to bear adequate directions for use, and they were not entitled to any exemption from that requirement.

DISPOSITION: 8-14-62, 9-25-62, 11-5-62. Default—2 devices destroyed; 2 devices delivered to the Food and Drug Administration.

7619. Micro-Dynameter devices (2 seizure actions). (F.D.C. Nos. 47819, 47829. S. Nos. 69-153 T, 75-332 T.)

QUANTITY: 2 devices, at Juneau, Wis., and Carson City, Nev.

SHIPPED: Between about 1-1-58 and about 8-13-62, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "For Scientific Body Analysis The Ellis Micro-Dynameter Mfd. by Ellis Research Laboratories, Inc., Chicago U.S.A."

LIBELED: 8-8-62, 8-20-62; E. Dist. Wis., Dist. Nev.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for diagnosing disease; and 502(f) (1)—the labeling of the articles failed to bear adequate directions for use, and they were not entitled to any exemption from that requirement.

DISPOSITION: 9-10-62, 9-21-62. Default and consent in one action each—delivered to the Food and Drug Administration.

7620. Vibra-Dent electric toothbrush and attachments. (F.D.C. No. 47578. S. No. 36-145 T.)

QUANTITY: 229 boxes, each containing a vibrator, 4 attachable toothbrushes, and a gum massager, at New Orleans, La.

SHIPPED: 3-27-62, from New York, N.Y., by Chase Manufacturing Co., Inc.

LABEL IN PART: (Vibrator) "Vibra-Dent Electric Toothbrush and Gum Massager * * * Excel Newark, N.J. * * * Model D."

ACCOMPANYING LABELING: Leaflet entitled "How to Use Your Vibra-Dent Toothbrush and Gum Massager the best in a complete home dental treatment for every member of the family"; and card entitled "Business Reply Mail * * * Chase Manufacturing Co., Inc."

RESULTS OF INVESTIGATION: Examination showed the article to be an electrically-operated vibrator device, about the size and general shape of an electric razor. The toothbrush attachments and the soft, finger-shaped gum massager fitted individually onto the shaft extending from one end of the vibrator.

LIBELED: 5-3-62, E. Dist. La.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the device helped the user to reach every tooth surface to remove food and debris that often caused tooth decay, that the motor unit and cord unit were sealed, and that the device offered "the best in a complete home dental treatment"; and 502(f) (2)—the labeling of the article failed to bear adequate warnings against potential electric shock hazard resulting from immersion of the article in water by children or adults.

DISPOSITION: 11-6-63. Default—destruction.

DRUGS FOR VETERINARY USE

7621. Bicon medicated feed. (F.D.C. No. 49071. S. No. 45-388 V.)

QUANTITY: 4 drums, at Springdale, Ark., in possession of LuMar Laboratories.

SHIPPED: 3-5-63, from Charles City, Iowa.

LABEL IN PART: (Drum) "Lu Mar Bicon 100 Pounds For use as a growth stimulant, Stomachic Appetizer and to stimulate recovery after disease.

Active Ingredients: * * * Arsenic Trioxide 10% * * * Manufactured For Lu Mar Laboratories, Springdale, Arkansas * * * Caution Contains Arsenic * * * Directions for Chicks, Broilers, Fryers, Laying Birds, Poults, and Turkeys."

RESULTS OF INVESTIGATION: The article was relabeled as described above after its receipt at Springdale, Ark.

LIBELED: 6-7-63, W. Dist. Ark.

CHARGE: 502(a)—while held for sale, the label bore false and misleading representations that the article was adequate and effective for use as a growth stimulant, stomachic appetizer, and to stimulate recovery after disease in chicks, broilers, fryers, laying birds, poults, and turkeys; and 502(f) (1)—the labeling failed to bear adequate directions for use, since when mixed and fed as directed on its label the article did not act as a growth stimulant, stomachic appetizer, or to stimulate recovery after disease.

The article was also alleged to be adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 7-15-63. Default—destruction.

7622. Cattle supplement feed. (F.D.C. No. 49215. S. No. 27-627 X.)

QUANTITY: 75 50-lb. bags at Luverne, Minn.

SHIPPED: 6-10-63, from Spencer, Iowa, by Welco Feed Manufacturing Co., Inc.

LABEL IN PART: (Bag) "Sweet as Honey Cattle Supplement A-1 Roughage Fortifier * * * Manufactured by Welco Feed Mfg. Co., Inc. Spencer, Iowa."

RESULTS OF INVESTIGATION: Examination showed that the article contained diethylstilbestrol, varying from bag to bag, between 1.1 milligrams per pound to 10.66 milligrams per pound.

LIBELED: 8-8-63, Dist. Minn.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported and represented to possess; 502(e) (2)—the label of the article failed to bear the common or usual name of each active ingredient, since diethylstilbestrol was not declared; and 502(f)—the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use.

DISPOSITION: 9-20-63. Default—destruction.

7623. M-27 montmorillonite. (F.D.C. No. 48653. S. No. 21-540 V.)

QUANTITY: 644 100-lb. bags, at Greeley, Colo., in possession of Imperial Minerals Distributing Co.

SHIPPED: Between 9-28-62 and 12-13-62, from Imperial, Calif.

LABEL IN PART: (Bag) "M-27 Montmorillonite Imperial Minerals Distributing 9371 Ellen Ct. Denver 16, Colorado."

ACCOMPANYING LABELING: News letters entitled "Coop Scoop" containing an article entitled "M 27 Livestock Mineral Now on Sale," by Samuel F. Burkhalter, and bags labeled "Note: M 27 is unexcelled in controlling scours and coccidiosis."

RESULTS OF INVESTIGATION: Examination showed that the article was a grayish powdered substance.

The article was mined and bagged in California. The labels were furnished the packer by Samuel F. Burkhalter, t/a Imperial Minerals Distributing Co.

LIBELED: 3-4-63, Dist. Colo.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for scours and coccidiosis; and 502(f) (1)—the labeling failed to bear adequate directions for use of the article for abortions, scours, and coccidiosis, which were the conditions for which the article was offered in oral statements made by Samuel F. Burkhalter.

DISPOSITION: 9-18-63. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICES FOR HUMAN USE*

7624. Imitation drug. (F.D.C. No. 47332. S. No. 58-436 R.)

INFORMATION FILED: 3-26-63, N. Dist. Ill., against Jerome P. Borovik, t/a Bee Drug Co., Chicago, Ill.

ALLEGED VIOLATION: On 1-31-61, while quantities of *imitation Meticorten tablets* were being held for sale after shipment in interstate commerce, the defendant caused such tablets to be offered for sale and sold, which act resulted in the drug being adulterated.

*See also Nos. 7601, 7607, 7608.

CHARGE: 501(d)(2)—while held for sale, *imitation Meticorten tablets* were substituted for Meticorten tablets.

PLEA: Guilty.

DISPOSITION: 5-20-63. \$250 fine, plus costs.

7625. Calcium gluconate injection. (F.D.C. No. 48819. S. No. 21-951 V.)

QUANTITY: 15 ctns., each containing 25 10-cc. ampuls, at Albuquerque, N. Mex.

SHIPPED: 8-20-62, from Decatur, Ill., by Taylor Pharmacal Co.

LABEL IN PART: (Ampul) "Ampul Calcium Gluconate U.S.P. * * * Distributed by New Mexico Pharmacal Co., Albuquerque, New Mexico."

LIBELED: 3-21-63, Dist. N. Mex.

CHARGE: 501(b)—when shipped, the quality and purity of the article fell below the standard for *calcium gluconate injection* set forth in the United States Pharmacopeia since the article contained pyrogens.

DISPOSITION: 4-23-63. Default—destruction.

7626. Liverfol-B-12 injection. (F.D.C. No. 48638. S. No. 42-471 V.)

QUANTITY: 29 10-cc. vials at Camden, N.J.

SHIPPED: 7-23-62, from Philadelphia, Pa.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 50 percent of the declared amount of vitamin B₁₂.

LIBELED: 2-20-63, Dist. N.J.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; and 502(a)—the label statement "Each cc. contains Liver Injection N.F. Vitamin B-12 activity equivalent to 20 micrograms cyanocobalamin per cc. 0.5 cc. Vitamin B-12 60 micrograms" was false and misleading as applied to a product containing less than the declared amount of vitamin B₁₂.

DISPOSITION: 4-19-63. Default—destruction.

7627. Rubber prophylactics. (F.D.C. No. 48372. S. Nos. 12-612/13 V.)

QUANTITY: 34 ctns., 72 2-unit boxes each, at Ottawa, Ill.

SHIPPED: 10-12-62, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Box) "Tops Prophylactics * * * M & M Rubber Co. Kansas City 8, Mo." and "Spartans * * * Prophylactics Package of One Sold for the Prevention of Disease Only * * * M & M Rubber Co. Kansas City 8, Mo."

LIBELED: 11-26-62, N. Dist. Ill.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statements "Prophylactics" and "Sold For The Prevention of Disease Only" were false and misleading as applied to a product containing holes.

DISPOSITION: 1-4-63. Default—destruction.

7628. Rubber prophylactics. (F.D.C. No. 48359. S. No. 24-586 V.)

QUANTITY: 50 ctns. of 46 3-unit pkgs. each at Detroit, Mich.

SHIPPED: 10-5-62, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Swan Super Thin Reservoir Prophylactics Sold for the Prevention of Disease Only, M&M Rubber Co., Kansas City 8, Mo."

RESULTS OF INVESTIGATION: Examination of 200 prophylactics showed that 4, or 2.0 percent, were defective in that they contained holes.

LIBELED: 11-19-62, E. Dist. Mich.

CHARGE: 501(c)—when shipped, the quality of the article differed from that which it purported to possess; and 502(a)—the label statement "Sold for the Prevention of Disease Only" was false and misleading as applied to a product containing holes.

DISPOSITION: 1-7-63. Default—destruction.

7629. Rubber prophylactics. (F.D.C. No. 48859. S. No. 72-420 V.)

QUANTITY: 63 ctns., each containing 48 plastic 3-unit pkgs., at Monticello, Miss.

SHIPPED: 3-13-63, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Zip Prophylactics J. B. Distributors P.O. Box 3 Brookhaven, Miss. Sold for the prevention of disease."

RESULTS OF INVESTIGATION: Examination showed that 3 percent of the prophylactics examined were defective in that they contained holes.

LIBELED: 4-22-63, S. Dist. Miss.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "Sold for the prevention of disease" was false and misleading.

DISPOSITION: 5-14-63. Default—destruction.

7630. Rubber prophylactics. (F.D.C. No. 49279. S. Nos. 47-194/5 X.)

QUANTITY: 4 cases, each containing 3,600 units in pkgs. of 3 units, and 4 cases, each containing 3,600 units in pkgs. of 2 units, at Hot Springs, Ark.

SHIPPED: 7-18-63, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Big Chief Transparent Prophylactics Sold For The Prevention Of Disease Only—H. L. Blake Co., Inc. * * * Hot Springs, Arkansas."

RESULTS OF INVESTIGATION: Examination showed that approximately 3 percent of the units in 3-unit packages and approximately 1 percent of the units in 2-unit packages contained holes.

LIBELED: 8-16-63, W. Dist. Ark.

CHARGE: 501(c)—when shipped, the quality of the articles fell below that which they were purported to possess; and 502(a)—the label statements on the packages "Sold For The Prevention Of Disease Only" were false and misleading as applied to products containing holes.

DISPOSITION: 10-1-63. Default—destruction.

7631. Rubber prophylactics. (F.D.C. No. 49282. S. No. 28-784 X.)

QUANTITY: 25 ctns., each containing 12 boxes, each box containing 4 3-unit pkgs., at Nashville, Tenn.

SHIPPED: 8-6-63, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Tops Cap Type Rubber Glan Sheaths M & M Rubber Company, Kansas City 8, Mo."

RESULTS OF INVESTIGATION: Examination showed that approximately 0.69 percent of the articles contained holes.

LIBELED: 8-22-63, M. Dist. Tenn.

CHARGE: 501(c)—when shipped, the quality of the article differed from that which it was purported to possess.

DISPOSITION: 10-23-63. Default—destruction.

7632. Rubber prophylactics. (F.D.C. No. 48659. S. No. 4-621 V.)

QUANTITY: 48 ctns., each containing 48 3-unit pkgs., at Norfolk, Va.

SHIPPED: 1-16-63, from Newark, N.J., by Circle Rubber Corp.

LABEL IN PART: (Pkg.) "Essex * * * Plain Ends Super Thin-Transparent Prophylactics * * * Package of Three Manufactured by Circle Rubber Corporation, Newark, N.J."

RESULTS OF INVESTIGATION: Examination showed that 5.8 percent contained holes.

LIBELED: 3-6-63, E. Dist. Va.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "Sold For The Prevention of Disease Only" was false and misleading as applied to an article containing holes.

DISPOSITION: 3-26-63. Default—destruction.

7633. Rubber prophylactics. (F.D.C. No. 48346. S. No. 15-389 V.)

QUANTITY: 31 ctns. of 12 boxes each, each box containing 12 individually packaged units, at Anchorage, Ky.

SHIPPED: 9-25-62, from North Kansas City, Mo., by Dean Rubber Manufacturing Co.

LABEL IN PART: (Ctn. and box) "Peacocks the Original Reservoir ends Rolled No. 18 a Product of Dean Rubber Manufacturing Co. North Kansas City, Mo."; (pkg.) "An Aid In Preventing Venereal Diseases."

RESULTS OF INVESTIGATION: Examination of 225 prophylactics showed that 3, or 1.3 percent, were defective in that they contained holes.

LIBELED: 11-1-62, W. Dist. Ky.; amended libel 11-19-62.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "An Aid In Preventing Venereal Diseases" was false and misleading as applied to an article containing holes.

DISPOSITION: 5-7-63. Default—delivered to the Food and Drug Administration.

7634. Rubber prophylactics. (F.D.C. No. 49285. S. No. 11-089 X.)

QUANTITY: 20 ctns., each containing 12 12-unit pkgs., at Rochester, N.Y.

SHIPPED: 6-20-63 and 7-31-63, from Cleveland, Ohio, by Schaeffer Products Co., Inc.

LABEL IN PART: (Pkg.) "One Dozen Rolled La Vita Reservoir End Prophylactics Packed By Schaeffer Products Co. Cleveland, Ohio."

RESULTS OF INVESTIGATION: Examination showed that approximately 2 percent of the articles contained holes.

LIBELED: 8-28-63, W. Dist. N.Y.

CHARGE: 501(c)—when shipped, the quality of the article differed from that which it was purported to possess; and 502(a)—the label statements, (pkg.)

"Sold Only To Prevent Disease" and (ctn.) "Sold For Prevention of Disease Only," were false and misleading as applied to a product containing holes.

DISPOSITION: 11-5-63. Default—destruction.

DRUGS FOR VETERINARY USE*

7635. Medicated feed. (F.D.C. No. 47162. S. No. 7-483 T.)

QUANTITY: 120 100-lb. bags at Mansfield, Mass.

SHIPPED: 1-4-62, from St. Johnsbury, Vt., by Ralston Purina Co.

LABEL IN PART: (Bag) "100 Lbs. Net Purina Capena MP Medicated * * * Active Drug Ingredient: Amprolium * * * 0.0125% Ralston Purina Co. St. Louis, Mo. B-7379."

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than the declared amount of the active drug ingredient, amprolium.

LIBELED: 2-21-62, Dist. Mass.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported to possess; and 502(a)—the label statement "Active Drug Ingredient: Amprolium * * * 0.0125%" was false and misleading.

DISPOSITION: 2-20-63. Consent—destruction.

7636. Medicated feed. (F.D.C. No. 48703. S. No. 34-354 V.)

QUANTITY: 207 50-lb. bags at Superior, Wis.

SHIPPED: Between 12-18-61 and 5-18-62, from St. Paul, Minn.

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 76 percent of the declared amount of nitrophenide.

LIBELED: 2-13-63, W. Dist. Wis.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Nitrophenide 0.020%" was false and misleading as applied to a product containing less than the declared amount of nitrophenide.

DISPOSITION: 3-29-63. Default—distributed to charitable institutions for use as animal feed.

DRUGS AND DEVICE ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS AND DEVICE FOR HUMAN USE**

7637. Vitamin A capsules. (F.D.C. No. 48842. S. Nos. 25-337/38 V.)

QUANTITY: 1,584 100-capsule btls. of 25,000-U.S.P.-Unit capsules and 360 100-capsule btls. of 50,000-U.S.P.-Unit capsules, at Holland, Mich., in possession of The DePree Co.

SHIPPED: Between 10-16-62 and 11-15-62, from Newark, N.J.

LABEL IN PART: "De Pree Vitamin A Capsules 25,000 U.S.P. Units [or "50,000 U.S.P. Units"] * * * Distributed by Nutritional Products Div. The De Pree Company, Holland, Michigan."

ACCOMPANYING LABELING: Loose labels reading as above.

*See also Nos. 7609, 7622.

**See also Nos. 7607, 7608, 7610, 7615, 7617-7620, 7626-7630, 7632-7634.

RESULTS OF INVESTIGATION: The articles had been repacked and labeled as above by the dealer.

LIBELED: 4-8-63, W. Dist. Mich.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the articles were adequate and effective for the treatment of night blindness and conditions of the eyes, skin, and mucous membranes.

DISPOSITION: 4-17-63. None of the drug articles named in the label were available for seizure, but 14,000 labels were seized. The court, having been shown that The DePree Co. was sole owner of the articles seized and did not desire to contest the matter, entered a decree of condemnation and the labels which had been seized were destroyed.

7638. **Alguemail toothpaste.** (F.D.C. No. 48054. S. No. 75-516 T.)

QUANTITY: 5,000 ctns., each containing 1 tube, at San Francisco, Calif.

SHIPPED: 3-26-62, by Laboratoires S.I.T.S.A., 15 Rue Des Champs—Asnieres (Seine), France.

ACCOMPANYING LABELING: Leaflets in each carton reading in part "Alguemail Toothpaste * * * Of late years, scientific researches tend to show that sea water from which it seems all life originated, has marvellous regenerative qualities."

LIBELED: 8-23-62, N. Dist. Calif.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective for preventing tooth decay, tartar formation, pyorrhea, and that the article had regenerative, styptic, and healing qualities; 502(b)—the label failed to bear (1) the name and address of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents; and 502(c)—the label contained representations in a foreign language and the information required to appear on the label under 502(b) (1) (2) and 502(e) (2), namely, the name and place of business of the manufacturer, packer, or distributor, an accurate statement of the quantity of contents, and the common or usual name of each active ingredient, did not appear on the label in that foreign language.

DISPOSITION: 4-22-63. Consent—claimed by Bowerman's Pharmacy, Inc., San Francisco, Calif., and relabeled.

7639. **Violet ray generator device.** (F.D.C. No. 48091. S. No. 60-293 T.)

QUANTITY: 9 devices at New Orleans, La.

SHIPPED: 6-13-62, from Chicago, Ill., by Arrow Glass Co.

LABEL IN PART: (Device) "Pat. Pending BD #10."

ACCOMPANYING LABELING: Leaflet entitled "Violetta The Superlative High Frequency Violet Ray Generator."

RESULTS OF INVESTIGATION: The article was a cylindrical plastic device, tapering to an opening at one end to receive a detachable glass electrode with a metal tip, and having attached to the other end an electric cord and plug for connection to house current for use of the device. Electrical energy was transmitted through application of the electrode to the body.

LIBELED: 9-18-62, E. Dist. La.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective as a treatment for aiding one's health and beauty, assisting in bringing and keeping good health, relieving muscular aches and pains, and improving circulation to overcome or prevent scalp diseases.

DISPOSITION: 1-10-63. Default—destruction.

DRUG FOR VETERINARY USE*

7640. Ferro-Lac swine formula. (F.D.C. No. 48684. S. No. 47-888 V.)

QUANTITY: 75 5-lb. pkgs. at Springfield, Ill.

SHIPPED: 10-9-62, from Springfield, Mo., by Naremcro, Inc.

LABEL IN PART: (Pkg.) "Naremcro Ferro-Lac Swine Formula (Concentrate)—Active Drugs: Sodium Propionate 45 gm/lb * * * Phthalamic Acid Sodium 20 gm/lb Methylrosaniline Chloride 1500 mg/lb. Naremcro * * * Springfield, Mo."

ACCOMPANYING LABELING: Leaflets entitled "How To Use Ferro-Lac Swine Formula" and "Naremcro, Inc. Animal and Poultry Health Products."

LIBELED: 1-22-63, S. Dist. Ill.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was adequate and effective as a treatment for use in baby pigs and young pigs in overcoming scours, anemia, enteritis, necro, dysentery, gut edema, tail biting associated with anemia, certain nutrient deficiencies, iron deficiency anemia, and for use in increasing immunization potential.

DISPOSITION: 3-25-63. Default—destruction.

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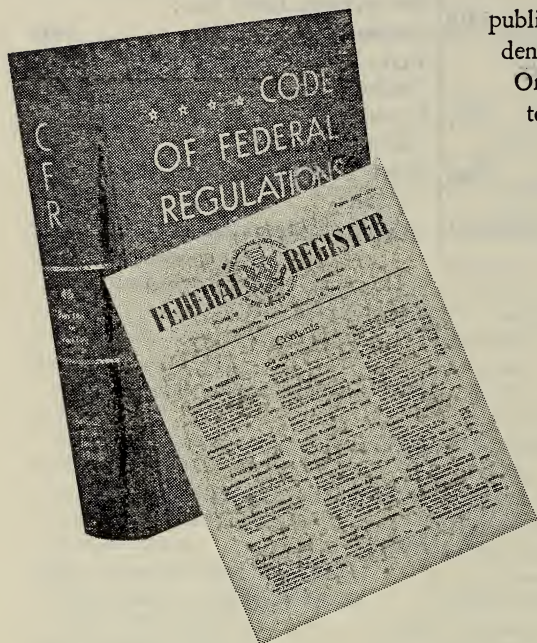
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U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

7641-7680

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b)(1), and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., July 20, 1964.

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VIOLATIVE SALES OF PRESCRIPTION DRUGS

7641. (F.D.C. No. 48542. S. Nos. 4-650/1 T.)

INFORMATION FILED: 7-22-63, W. Dist. Va., against Cornelius Johnson, t/a Sara's Truck Stop & Restaurant, Danville, Va., and C. P. Whaley (employee).

CHARGE: On 1-23-63, *amphetamine sulfate tablets* and *tablets containing a mixture of dextro-amphetamine sulfate and amobarbital* were each dispensed once without a prescription.

PLEA: Nolo contendere by Whaley; guilty by Johnson.

DISPOSITION: 9-10-63. Whaley—\$250 fine, and probation for 3 years. 9-23-63. Johnson—\$250 fine, and probation for 3 years.

7642. (F.D.C. No. 49154. S. Nos. 17-055/6 V.)

INDICTMENT RETURNED: 9-24-63, E. Dist. Ky., against Willis Creech and Edward Creech, Newport, Ky.

CHARGE: On 1-25-63, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty by each defendant to 1 count.

DISPOSITION: 9-26-63. Edward Creech—6 months in jail. 1-10-64. Willis Creech—4 months in jail.

7643. (F.D.C. No. 49155. S. Nos. 15-653 V, 17-020 V, 17-040 V, 17-422 V.)

INDICTMENT RETURNED: 9-24-63, E. Dist. Ky., against William A. Gabbard, Newport, Ky.

CHARGE: Between 2-12-63 and 2-14-63, *amphetamine sulfate tablets* were dispensed 3 times and *Nembutal Sodium capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 9-27-63. Imprisonment for 12 months.

7644. (F.D.C. No. 49153. S. Nos. 17-386 V, 17-052 V.)

INDICTMENT RETURNED: 9-24-63, E. Dist. Ky., against Willie Benjamin Pryor, Covington, Ky.

CHARGE: Between 1-19-63 and 1-23-63, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 10-2-63. Imprisonment for 6 months.

7645. (F.D.C. No. 48876. S. Nos. 58-405/9 T.)

INFORMATION FILED: 5-6-63, W. Dist. Ky., against Harlan French, t/a Valley Truck Stop, Valley Station, Ky.

CHARGE: Between 6-4-62 and 6-8-62, *amphetamine sulfate tablets* were dispensed 4 times and *dextro-amphetamine sulfate capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10-18-63. \$100 fine, and probation for 1 year.

7646. (F.D.C. No. 48535. S. Nos. 36-342 T, 36-344 T.)

INFORMATION FILED: 5-3-63, N. Dist. Miss., against Jackie Turner Wood, t/a Jackie Wood Truck Stop, Boyle, Miss., and Joe H. Garrett (employee).

CHARGE: Between 1-26-62, and 2-20-62, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty by Wood to 2 counts; by Garrett to 1 count.

DISPOSITION: 11-15-63. Wood—\$200 fine, and probation for 3 years; Garrett—probation for 3 years.

7647. (F.D.C. No. 48908. S. Nos. 59-863/7 T.)

INFORMATION FILED: 7-19-63, N. Dist. Ala., against **Pearce S. Johnson, M.D., Birmingham, Ala.**

CHARGE: Between 8-23-62 and 11-27-62, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 11-18-63. Sentence of 1 year and 1 day in prison suspended, and probation for 2 years.

7648. (F.D.C. No. 48882. S. Nos. 1-970/1 T.)

INFORMATION FILED: 6-24-63, N. Dist. Ga., against **Carl B. Eskew, Atlanta, Ga.**

CHARGE: Between 2-10-62 and 2-13-62, *amphetamine sulfate tablets* and *tablets containing a mixture of dextro-amphetamine sulfate and amphetamine sulfate* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11-22-63. Sentence of 6 months in prison.

7649. (F.D.C. No. 48558. S. Nos. 657 T, 76-908 T.)

INFORMATION FILED: 5-15-63, E. Dist. S.C., against **Billy H. Blackmon and Jimmie E. Blackmon (employees of a truck stop), Society Hill, S.C.**

CHARGE: Between 5-4-62 and 5-24-62, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty by each defendant to 1 count.

DISPOSITION: 12-2-63. Each defendant—probation for 5 years.

7650. (F.D.C. No. 47340. S. Nos. 86-808/10 T.)

INFORMATION FILED: 9-30-63, M. Dist. N.C., against **Frank Albert Mays (truck stop operator), Reidsville, N.C.**

CHARGE: On 8-7-62, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12-5-63. Sentence of 9 months in prison.

7651. (F.D.C. No. 48557. S. Nos. 77-009/10 T, 77-021/3 T.)

INFORMATION FILED: 7-9-63, M. Dist. N.C., against **William R. Cook, t/a Evelyn's Truck Stop, Stokesdale, N.C.**

CHARGE: Between 5-29-62 and 6-18-62, *amphetamine sulfate tablets* were dispensed 3 times and *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12-5-63. Sentence of 2 years in prison.

7652. (F.D.C. No. 48881. S. Nos. 89-261/63 T.)

INFORMATION FILED: 9-9-63, N. Dist. Ind., against **J. B. Mangrum** (operator of a truck stop), New Haven, Ind.

CHARGE: Between 7-25-62 and 10-2-62, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 12-11-63. Sentence of 6 months in prison suspended, \$500 fine, and probation for 6 months.

7653. (F.D.C. No. 49169. S. No. 22-761 V.)

INFORMATION FILED: 10-29-63, Dist. N. Mex., against **Dale Branton** (employee of a truck stop), Las Cruces, N. Mex.

CHARGE: On 2-8-63, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 1-3-64. Sentence of probation for 1 year.

7654. (F.D.C. No. 48548. S. Nos. 9-471 T, 10-085 T.)

INFORMATION FILED: 5-20-63, W. Dist. Pa., against **David N. Ingram, M.D.**, Houston, Pa.

CHARGE: Between 1-30-62 and 3-14-62, *amphetamine sulfate tablets* and *Carbital Kapseals* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 1-21-64. \$500 fine, plus costs, and probation for 1 year.

7655. (F.D.C. No. 49170. S. No. 54-705 V.)

INFORMATION FILED: 10-29-63, W. Dist. Mo., against **Fred Clements, Farmers Branch, Tex.**

CHARGE: On 1-25-63, *amphetamine sulfate tablets* were dispensed once at Joplin, Mo., without a prescription.

PLEA: Guilty.

DISPOSITION: 3-9-64. Probation for 1 year, plus court costs.

7656. (F.D.C. No. 48914. S. Nos. 16-805 T, 15-342 V, 15-346 V, 15-349 V, 16-621 V, 16-623 V.)

INFORMATION FILED: 5-29-63, S. Dist. Ind., against **George H. Springstun, M.D.**, Oaktown, Ind.

CHARGE: Between 7-19-62 and 5-8-63, *dextro-amphetamine hydrochloride tablets* were dispensed 4 times and *tablets containing a mixture of dextro-amphetamine sulfate and amphetamine sulfate* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 9-17-63. \$1,800 fine, plus costs.

7657. (F.D.C. No. 48890. S. Nos. 72-601 T, 72-603 T, 72-606/9 T, 15-403 V.)

INFORMATION FILED: 7-5-63, W. Dist. Ky., against **Thomas J. Keith, t/a Light House Service Station, Bowling Green, Ky.**, and **Samuel P. Arnett** (employee).

CHARGE: Between 6-8-62 and 10-5-62, *dextro-amphetamine sulfate capsules* were dispensed 3 times and *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty by Keith to 5 counts; by Arnett to 2 counts.

DISPOSITION: 11-11-63. Keith—\$500 fine; Arnett—\$200 fine.

7658. (F.D.C. No. 48926. S. Nos. 14-805 T, 14-808/9 T, 14-812/13 T.)

INFORMATION FILED: 8-9-63, N. Dist. Ill., against David K. Gordon, t/a Gordon Drugs, Chicago, Ill., and George G. Gagola (apprentice pharmacist), and Joseph Winograd (apprentice pharmacist).

ALLEGED VIOLATION: Between 6-6-62 and 7-11-62, *dextro-amphetamine sulfate capsules* were dispensed 3 times, and *Seconal Sodium capsules* and *secobarbital sodium capsules* were each dispensed once without a prescription.

PLEA: Nolo contendere by the defendants to 1 count each involving *dextro-amphetamine sulfate capsules*; by Gordon to the count involving *Seconal Sodium capsules*; and by Winograd to the count involving *sodium secobarbital capsules*.

DISPOSITION: 2-20-64. Gordon—\$100 fine, plus costs, and probation for 1 year; Gagola—probation for 1 year; and Winograd—probation for 1 year.

7659. (F.D.C. No. 46725. S. Nos. 60-470/4 R.)

INFORMATION FILED: 4-3-62, N. Dist. Ala., against Leon Rayburn, t/a Rayburn Pharmacy, Guntersville, Ala.

CHARGE: Between 2-27-61 and 3-22-61, *Benzedrine Sulfate tablets* were dispensed 4 times and *meprobamate tablets* were dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: 1-6-64. The court found the defendant guilty on the basis of stipulations signed by the defendant on 12-26-63, and placed the defendant on probation for 1 year.

7660. (F.D.C. No. 48190. S. Nos. 6-542/4 T, 6-548/50 T, 6-555 T, 7-551 T, 7-553/4 T, 61-776 T.)

INFORMATION FILED: 3-28-63, Dist. Mass., against Riverway Drug Store, Inc., Boston, Mass., and Herman Shifman (president-treasurer).

CHARGE: Between 12-5-61 and 4-9-62, *Butisol Sodium tablets* and *Butazolidin capsules* were each dispensed 4 times, and *Benzedrine Sulfate tablets* were dispensed 3 times upon requests for prescription refills without obtaining authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 10-21-63. Corporation—\$1,000 fine; Shifman—6 months in prison suspended, and probation for 2 years.

7661. (F.D.C. No. 48540. S. Nos. 18-168/9 T, 18-173/5 T, 18-177 T, 18-179/80 T, 20-320 T.)

INFORMATION FILED: 7-11-63, S. Dist. Tex., against O.S.T. Pharmacy, Inc., Houston, Tex., and Charles F. Napoletan (president).

CHARGE: Between 5-2-62 and 7-20-62, *Dexedrine Sulfate tablets* and *penicillin tablets* were each dispensed 3 times, *meprobamate tablets* were dispensed twice, and *secobarbital sodium capsules* were dispensed once upon requests for prescription refills without obtaining authorization by the prescriber.

PLEA: Not guilty.

DISPOSITION: The case came to trial before the court and jury on 9-10-63. At the conclusion of the trial, the jury returned a verdict of guilty on 5 counts, and not guilty on 4 counts. On 11-30-63, the defendants were sentenced as follows: Corporation—\$500 fine; Napoletan—5 years in prison suspended, and \$500 fine.

7662. (F.D.C. No. 48924. S. Nos. 5-982 T, 3-130/3 V, 3-742/3 V.)

INDICTMENT RETURNED: 10-30-63, N. Dist. W. Va., against Harold John Elsey, t/a Smith's Pharmacy, Clarksburg, W. Va., and Earl F. Gower (pharmacist).

CHARGE: Between 8-24-62 and 11-7-62, *Dexedrine Sulfate tablets* were dispensed 5 times and *pentobarbital sodium capsules* were dispensed twice, upon requests for prescription refills without authorization from the prescriber.

PLEA: Guilty by Gower to 1 count involving *Dexedrine Sulfate tablets*; and by Elsey to 4 counts involving *Dexedrine Sulfate tablets* and 2 counts involving *pentobarbital sodium capsules*.

DISPOSITION: 11-18-63. Each defendant placed on probation for 2 years.

7663. (F.D.C. No. 49685. S. Nos. 13-101 V, 13-106 V, 13-109/10 V.)

INFORMATION FILED: 3-5-64, N. Dist. Ill., against Lieberman Pharmacy, Inc., Chicago, Ill., Maurice Lieberman (president and pharmacist), and Danny S. Lieberman (secretary and apprentice pharmacist).

RESULTS OF INVESTIGATION: Investigation showed that the *secobarbital sodium capsules* involved in 1 count had been fabricated locally using secobarbital sodium powder shipped from Indianapolis, Ind.

CHARGE: Between 10-17-62 and 12-14-62, *Dexedrine Sulfate tablets* and *secobarbital sodium capsules* were each dispensed twice without a prescription.

PLEA: Nolo contendere by each defendant to 1 count involving tablets and to 1 count involving capsules.

DISPOSITION: 3-26-64. Corporation—\$200 fine, plus costs; Maurice Lieberman—\$50 fine; and Danny S. Lieberman—\$50 fine.

7664. (F.D.C. No. 49529. S. No. 65-332 V.)

INFORMATION FILED: 1-23-64, M. Dist. Tenn., against Glenda Sara Pierson, t/a Heffernan's Apothecary, Nashville, Tenn.

CHARGE: On 5-13-63, *Dexedrine Sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 3-3-64. Probation for 1 year.

7665. (F.D.C. No. 49161. S. No. 17-115 T.)

INFORMATION FILED: 11-4-63, S. Dist. Ohio, against Samuel A. Ladig, Columbus, Ohio.

CHARGE: On 8-23-61, *desoxyephedrine hydrochloride tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12-23-63. Sentence of 1 hour in the custody of the marshal.

7666. (F.D.C. No. 48916. S. Nos. 32-422 T, 32-424 T, 32-428 T.)

INFORMATION FILED: 8-26-63, S. Dist. Calif., against Norman Charles Title and Julius Lieberman (pharmacists), and Walter Bilski (drug clerk), Los Angeles, Calif.

CHARGE: Between 3-13-62 and 4-16-62, *Equanil tablets* were dispensed 3 times upon requests for prescription refills without obtaining authorization from the prescriber.

PLEA: Nolo contendere by each of the defendants to 1 count.

DISPOSITION: 12-10-63. Each defendant fined \$250.

7667. (F.D.C. No. 48566. S. Nos. 19-841 V, 19-843/50 V.)

INFORMATION FILED: 6-4-63, E. Dist. Okla., against Ted M. Berry, t/a Berry Drug Store, Henryetta, Okla.

CHARGE: Between 9-18-62 and 10-3-62, *meprobamate tablets* were dispensed 5 times, *penicillin G potassium tablets* were dispensed twice and *dextro-amphetamine sulfate capsules* and *Dexedrine Spansule capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6-10-63. \$450 fine.

7668. (F.D.C. No. 48896. S. Nos. 19-682/93 V.)

INFORMATION FILED: 8-13-63, E. Dist. Tex., against Hugh R. Tobin, t/a Tobin Drug Store, Denton, Tex., and Melvin D. Vinson (pharmacist).

CHARGE: Between 11-13-62 and 12-11-62, *meprobamate tablets* were dispensed 9 times, *Dexedrine Sulfate tablets* were dispensed twice and *prednisolone tablets* were dispensed once without a prescription.

PLEA: Guilty by Tobin to 5 counts; by Vinson to 8 counts.

DISPOSITION: 11-4-63. Each defendant—\$100 fine suspended and probation for 1 year.

7669. (F.D.C. No. 48521. S. Nos. 56-961 T, 56-962 T.)

INDICTMENT RETURNED: 10-21-63, S. Dist. Tex., against Marvin Lee Nichols, t/a Nichols Westside Pharmacy, Corpus Christi, Tex.

CHARGE: Between 2-27-62 and 3-3-62, *meprobamate tablets* were dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 1-22-64. \$500 fine.

7670. (F.D.C. No. 48518. S. Nos. 56-981 T, 56-983 T.)

INDICTMENT RETURNED: 10-21-63, S. Dist. Tex., against Charles A. Nichols, t/a Nichols Southside Pharmacy, Corpus Christi, Tex.

CHARGE: Between 2-27-62 and 3-5-62, *meprobamate tablets* were dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 1-22-64. \$350 fine.

7671. (F.D.C. No. 46720. S. Nos. 37-959 R, 37-994 R, 80-101 R.)

INFORMATION FILED: 5-4-62, E. Dist. Pa., against West Spruce Pharmacy (a partnership), Philadelphia, Pa., Irving I. Gasmer (partner), and Raymond R. Rosenthal (pharmacist).

CHARGE: Between 3-6-61 and 5-9-61, *Metandren Linguets* were dispensed twice and *Seconal Sodium capsules* were dispensed once upon requests for prescription refills without obtaining authorization by the prescriber.

PLEA: Nolo contendere by Rosenthal to 1 count involving *Metandren Linguets* and by the partnership and Gasmer to 1 count involving *Seconal Sodium capsules* and 1 count involving *Metandren Linguets*.

DISPOSITION: 11-14-63. Partnership—\$2,000 fine; each individual—probation for 1 year.

7672. (F.D.C. No. 49162. S. Nos. 3-176/80 V, 5-691/4 V.)

INDICTMENT RETURNED: 10-30-63, N. Dist. W. Va., against George Bowers Rice, t/a Rice-Rexall Drug Store, Shinnston, W. Va., and John Harrison Rice (pharmacist).

CHARGE: Between 1-30-63 and 4-4-63, *Miltown tablets* were dispensed 5 times and *secobarbital sodium capsules* were dispensed 4 times upon requests for prescription refills without obtaining authorization by the prescriber.

PLEA: Guilty by G. B. Rice to 3 counts; by J. H. Rice to 6 counts.

DISPOSITION: 11-18-63. Each defendant—sentence of probation for 2 years.

7673. (F.D.C. No. 49152. S. No. 17-387/8 V.)

INDICTMENT RETURNED: 9-24-63, E. Dist. Ky., against Thomas McQueary, Newport, Ky.

CHARGE: On 1-20-63, *Nembutal Sodium capsules* and *amphetamine sulfate tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 9-29-63. Imprisonment for 6 months.

7674. (F.D.C. No. 48150. S. Nos. 5-225/6 T, 5-228 T, 5-231 T, 5-233 T, 5-239 T.)

INFORMATION FILED: 2-25-63, E. Dist. Va., against Godwin H. Rapoport, t/a Washington Pharmacy, Portsmouth, Va., and Charles D. Stowe (pharmacist).

CHARGE: Between 4-10-62 and 6-13-62, *pentobarbital sodium capsules* and *Seconal Sodium capsules* were each dispensed 3 times upon requests for prescription refills without obtaining authorization by the prescriber.

PLEA: Guilty by each defendant to 3 counts.

DISPOSITION: 11-6-63. \$300 fine against each defendant.

7675. (F.D.C. No. 48894. S. Nos. 687 T, 87-814 T.)

INFORMATION FILED: 10-24-63, N. Dist. Ga., against Bruce E. Moore, Atlanta, Ga.

CHARGE: Between 7-12-62 and 8-28-63, *pentobarbital sodium capsules* and *Miltown tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11-22-63. Sentence of 6 months in prison.

7676. (F.D.C. No. 48892. S. Nos. 20-682 T, 20-688 T.)

INFORMATION FILED: 9-13-63, S. Dist. Tex., against Thomas P. McKee, t/a McKee's Pharmacy, Raymondville, Tex.

CHARGE: Between 5-22-62 and 6-26-62, *penicillin tablets* and *thyroid tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11-12-63. \$100 fine.

7677. (F.D.C. No. 48564. S. Nos. 54-881 T, 54-883 T, 54-885 T, 54-888/9 T, 87-781 T, 87-783 T, 87-785/8 T.)

INFORMATION FILED: 11-20-63, S. Dist. Fla., against Dixie Pharmacy (a partnership), Jacksonville, Fla., and Charles O. Mitchell, Sr. (partner), Paul Guerrant (employee), Burness V. Padgett (pharmacist), and John S. Bernreuter (pharmacist).

CHARGE: Between 1-31-62 and 8-23-62, *penicillin tablets* were dispensed 5 times (counts 1-5) and *prednisone tablets* were dispensed 6 times (counts 6-11) without a prescription.

PLEA: Guilty by Dixie Pharmacy to counts 6-11; by Paul Guerrant to counts 1-4; by Charles O. Mitchell, Sr., to count 5; by Burness V. Padgett to counts 6, 9, and 11; and by John S. Bernreuter to count 10.

DISPOSITION: 12-20-63. Partnership—\$600 fine; each individual—probation for 2 years.

7678. (F.D.C. No. 47078. S. No. 46-841 R.)

INFORMATION FILED: 7-3-63, E. Dist. Mich., against Roy-Al Pharmacy (a partnership), Highland Park, Mich., and Roy I. Rosenthal (partner).

CHARGE: On 10-11-60, *penicillin G potassium tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12-13-63. Partnership—\$100 fine; individual—probation for 1 year.

7679. (F.D.C. No. 49531. S. Nos. 64-523/4 V.)

INFORMATION FILED: 2-14-64, S. Dist. Ohio, against Berry Pharmacy Co. (a corporation), New Richmond, Ohio, and Robert P. Berry (president and treasurer).

CHARGE: On 3-29-63, *reserpine tablets* and *Diuril tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 3-26-64. Corporation—\$300 fine; no sentence imposed against individual.

7680. (F.D.C. No. 48877. S. Nos. 15-171 T, 15-185 T, 57-621 T, 71-807 T, 71-811 T, 16-052 V.)

INFORMATION FILED: 7-22-63, M. Dist. Tenn., against H. A. Buchi (pharmacist), Nashville, Tenn.

CHARGE: Between 3-8-62 and 10-3-62, *Seconal Sodium capsules* and *Dexedrine Sulfate tablets* were dispensed 3 times each upon requests for prescription refills without authorization from the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 10-7-63. Probation for 30 days.

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Bilski, Walter:		sone tablets_	7677
Equanil tablets_	7666		

¹ (7659, 7661) Prosecution contested.

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¹ (7659, 7661) Prosecution contested.

U.S. Department of Health, Education, and Welfare
FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD,
DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug and Cosmetic Act]
7681-7740

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were alleged to be adulterated or misbranded, or otherwise violative of the Act, when introduced into and while in interstate commerce, when shipped to a holder of a guaranty, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default, consent, or in one case each, summary judgment, or judgment on the pleadings, and also involving in a number of cases, consent decrees of permanent injunction; (2) criminal proceedings which were terminated upon pleas of guilty and nolo contendere and, including in one case, the denial of a motion to dismiss the proceeding; and (3) injunction proceedings terminated upon the entry of permanent injunction by consent. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., July 29, 1964.

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* For omission of, or unsatisfactory, ingredients statements, see Nos. 7682, 7687, 7690, 7691, 7706, 7710, 7718, 7740; an imitation of, and sale under name of, another drug, No. 7709; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 7682, 7690, 7691, 7699, 7714.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN ALLEGED VIOLATIONS REPORTED IN D.D.N.J. NOS. 7681-7740

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia, or National Formulary), and its strength differed from or its quality or purity fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from that which it purported or was represented to possess: and Section 501(d)(2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b)(1), the article was in package form, and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium and its label failed to bear (1) the common or usual name of the drug, and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient including, whether active or not, the name and quantity or proportion of any derivative or preparation of arsenic contained therein; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(i)(3), the article was offered for sale under the name of another drug; Section 502(1), the article was composed wholly or in part of a kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or some derivative thereof, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; Section 503(b)(1), the article was a drug intended for use by man which was a habit-forming drug to which Section 502(d) applied, or because of its toxicity or other potentiality for harmful effect, or the collateral measures necessary to its use, was not safe for use except under the supervision of a practitioner licensed by law to administer such drug or was limited by an approved or effective application under Section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug, and it was dispensed contrary to the dispensing provisions of this Section; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application, or an approval of an application, filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUGS FOR HUMAN USE

7681. Dr. Taylor's Special Formula L. (F.D.C. No. 45517. Inj. No. 442. S. No. 31-108 R.)

QUANTITY: 225,000 capsules, of which 202,500 were contained in 15 bulk ctns. and the balance repacked into various size boxes and containers, at Dallas, Tex., in possession of Taylor Clinic.

SHIPPED: The ingredients of the article, namely, *Prunus armeniaca* and magnesium oxide, were shipped on 4-26-60 and 4-29-60, from Los Angeles, Calif., and New York, N.Y., to Preston-National Drug Co., Dallas, Tex., which manufactured the article and delivered it to the Taylor Clinic, on 6-6-60.

LABEL IN PART: (Ctn.) "Dr. Taylor's Special Formula 'L' Control #4E34 Package #6 (or other numbers) Date Received 6/6/60 * * *" and "Bulk Shipment In reordering Refer to Control No. 4E34 * * * Quantity 85,260 (in 5 ctns.) Each Capsule Contains: *Prunus Armeniacus* 200 mg. Magnesium Oxide 250 mg. Dosage: One capsule as needed as carminative and antacid, or as directed * * * Preston-National Drug Co. Dallas Chicago."

LIBELED: 3-17-61, N. Dist. Tex.

CHARGE: 502(f) (1)—while held for sale, the labeling of the article failed to bear adequate directions for use for the purpose for which it was intended, namely, internal cancer, the condition for which it was recommended and dispensed; and 505(a)—the article was a new drug which may not be introduced into interstate commerce, since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: On 4-17-61, Dr. Harry R. Taylor, t/a Taylor Clinic, appeared as claimant and filed an answer denying that the article was a new drug or was misbranded as alleged. Thereafter, written interrogatories were served by the Government upon the claimant and were subsequently answered by the claimant. On 8-6-62, the claimant having consented to the condemnation of the article and the entry of an injunction, a decree was entered condemning the article and releasing it under bond to be brought into compliance with the law, and permanently enjoining the claimant, his agents, employees, servants, representatives, and all other persons in active concert or participation with him from doing the following acts:

(a) causing to be introduced into interstate commerce, and causing to be manufactured, packaged, repackaged, labeled, sold, advertised, promoted, distributed, or used, the drug, "*Dr. Taylor's Special Formula L*," and any similar drug, including the drugs "Oratril" and "Laetrile," which are accompanied by any written, printed, or graphic matter representing such drugs to be adequate and effective for the treatment, cure, prevention, or mitigation of cancer;

(b) causing to be introduced into interstate commerce, and causing to be manufactured, packaged, repackaged, labeled, sold, advertised, promoted, distributed, or used, the drug, "*Dr. Taylor's Special Formula L*," and any similar drug, including the drugs "Oratril" and "Laetrile," which fail to bear in their labeling a statement of each purpose, disease, and condition for which the drug is intended to be used, together with sufficient information to enable the layman to safely and effectively medicate himself for each such purpose, disease, and condition;

(c) doing any act with respect to any such drug while such drug is held for sale after shipment in interstate commerce, which results in the drug being accompanied by written, printed, or graphic matter containing representations that it is adequate and effective for treatment, cure, prevention, or mitigation of cancer, or which results in the drug failing to bear in its labeling a statement of each purpose, disease, and condition for which the drug is intended together with sufficient information to enable the layman to safely and effectively medicate himself for each such purpose, disease, and condition;

(d) causing to be used "*Dr. Taylor's Special Formula L*" and any similar drug, including the drugs "Oratril" and "Laetrile," in the treatment of

cancer, and recommending, prescribing, advising, or in any manner indicating, whether by oral statements, written, printed, or graphic matter, or other means, that such drug may be used in the treatment of cancer;

(e) causing to be introduced into interstate commerce, and causing to be manufactured, packaged, repackaged, labeled, sold, advertised, promoted, distributed, prescribed, or used, any article which is designated by the name "*Dr. Taylor's Special Formula L*" or by any other name which uses the letter "L";

(f) causing to be introduced into interstate commerce, and causing to be manufactured, packaged, repackaged, labeled, sold, advertised, promoted, distributed, prescribed, or used, any drug containing the ingredients, *Prunus armeniaca* and magnesium oxide, or any drug containing similar ingredients, for any purpose other than as an antacid or carminative; and from doing any act, whether oral or otherwise, with respect to any drug which contains *Prunus armeniaca* and magnesium oxide, or any drug containing similar ingredients, while such drug is held for sale after shipment in interstate commerce, which results in such drug being manufactured, packaged, repackaged, labeled, sold, advertised, promoted, distributed, prescribed, or used, for any purpose other than as an antacid or carminative.

On 1-25-63, the claimant having failed to file the required bond for the release of the article, an order was entered directing that the article be destroyed.

7682. Various prescription drugs. (F.D.C. No. 48251. S. Nos. 603 V, 606 V, 608 V, 610/11 V.)

QUANTITY: 4,381 tablets and capsules at Lake City, Fla., in possession of Davis Professional Drugs.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some drugs) "Professional Sample" or "Complimentary."

RESULTS OF INVESTIGATION: Some of the articles were prescription drugs which had been repacked by the dealer into containers to which had been affixed labels bearing such brand names for the drugs as were indicative of their manufacture outside the State of Florida, and the names and addresses of manufacturers, packers, or distributors located outside the State of Florida.

Some of the articles were prescription drugs which had not been repacked at the time the articles were libeled and which had labels bearing such brand names for the drugs as were indicative of their manufacture outside the State of Florida bearing a "complimentary-not for sale" legend, and bearing the names and addresses of manufacturers, packers, or distributors located outside the State of Florida.

LIBELED: 11-5-62, M. Dist. Fla.

CHARGE: 502(a)—while held for sale, the words "Professional Sample" and "Complimentary," and similar wording on the labels of a number of the articles were false and misleading as applied to articles then in the possession of a repacker and intended for sale and not intended for use as "complimentary-not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)(1)—a number of the articles failed to bear a label containing the name or place of business of the manufacturer, packer, or distributor; 502(e)(1)—a number of the articles failed to bear the common or usual name of the drug; 502(f)(1)—the labeling of a number of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were drugs subject to the provisions

of 503(b) (1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the packages of the drug as required by regulations; 503(b) (4)—the labels of a number of the articles failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and 505(a)—a number of the articles were new drugs which may not be introduced or delivered for introduction into interstate commerce under the provisions of 505 since no approval of an application filed pursuant to 505 was effective with respect to such drug.

DISPOSITION: 5-20-63. Default—destruction.

7683. Liefcort. (F.D.C. No. 48274. S. Nos. 39-345/6 V.)

QUANTITY: 11 15-cc. btl. at Mountain Lakes, N.J.

SHIPPED: In August 1962, from Dorian, Quebec, Canada, by Endocrine Research Laboratories.

RESULTS OF INVESTIGATION: No analysis was made of this article. Analysis of other samples of the same product showed it to contain prednisone and estradiol, or prednisone, estradiol, and testosterone in quantities sufficient to cause the drug to be dangerous to health when used as directed.

LIBELED: 11-7-62, Dist. N.J.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to 505(b) was effective with respect to such drug, and it was not exempt from 505 since it did not comply with the regulations with respect to new drugs for investigational use.

DISPOSITION: 12-17-62. Default—destruction.

7684. Virac Rex solution. (F.D.C. No. 48209. S. Nos. 51-080/3 T.)

QUANTITY: 2 cases, each containing 24 individually ctnd. 4-oz. btl., plus 10 4-oz. btl., 6 1-gal. btl., 2 cases, 12 1-pt. btl. each, and 2 cases, 6 1-gal. btl. each, at Spokane, Wash.

SHIPPED: 8-1-61 and 8-30-62, from Portland, Oreg., by Ruson Laboratories, Inc.

LABEL IN PART: (Btl.) "Modern Iodine Solution Virac Rex Broad Spectrum Microbicide * * * Active Ingredients: Undecoylium Chloride Iodine 1.80% (Available elemental iodine—0.6%) * * * Ruson Laboratories, Inc., Portland 2, Oregon."

ACCOMPANYING LABELING: Brochure entitled "A surgical antiseptic and therapeutic agent Virac-Modern Iodine * * * Detailed Use and Dilution Recommendations."

LIBELED: 10-3-62, E. Dist. Wash.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce, since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 12-6-62. Default—destruction.

DRUG FOR VETERINARY USE

7685. Heifer and steer implants. (F.D.C. No. 48212. S. Nos. 49-338/9 T.)

QUANTITY: 2 jars containing a total of 266 *heifer implants*, and 2 jars containing a total of 200 *steer implants*, at Oakdale, Calif.

SHIPPED: During the years 1957, 1958, 1959, 1960, and 1962, from Rio Piedras, Puerto Rico.

LABEL IN PART: (Jar) "250 Heifer Implants, 120 Day Caution: New drug limited by federal law to clinical investigational use only (animal) under the supervision of Dr. G. E. Taylor * * * Pan American Laboratories, Rio Piedras, Puerto Rico" and "250 Steer Implants 120 Day Caution: New drug * * * Under supervision of Dr. Glenn E. Taylor, D.V.M."

RESULTS OF INVESTIGATION: The articles were shipped from Puerto Rico to a firm in Porterville, Calif., where the articles were relabeled and reshipped to Yosemite Veterinary Hospital & Supply, Modesto, Calif., who in turn relabeled the lots as described above and reshipped them to the dealer. Analysis showed that the articles consisted of hexestrol and androstanedione or hexestrol and testosterone.

LIBELED: 10-12-62, N. Dist. Calif.

CHARGE: 505(a)—the articles were a new drug which may not be introduced or delivered for introduction into interstate commerce under 505 in that an application filed pursuant to 505(b) was not effective with respect to such drug, and the articles were not being used for investigational purposes as declared on the labels.

The articles were alleged also to be adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 2-27-63. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE FOR WHICH NONE HAD BEEN ISSUED

DRUG FOR HUMAN USE

7686. Multidisk Sensitivity Discs. (F.D.C. No. 47966. S. Nos. 56-026/7 T.)

QUANTITY: 13 50-disc jars (Code No. 11-83D), and 13 50-disc jars (Code No. 11-110A), at New Hyde Park, N.Y.

SHIPPED: 6-5-62, from Chicago Heights, Ill., by Consolidated Laboratories, Inc.

LABEL IN PART: (Jar) "Multidisk Sensitivity Discs Code No. 11-83D * * * Lot 929 Exp. Date Apr 1963 * * * Chlortetracycline (A+) 30 Mcg Chloramphenicol (C+) 30 Mcg Erythromycin (E+) 15 Mcg Novobiocin (NV+) 30 Mcg Oleandomycin (OL+) 30 Mcg Penicillin (P+) 10 Units Oxytetracycline (T+) 30 Mcg Tetracycline (TE+) 30 Mcg," "Multidisk Sensitivity Discs Code No. 11-110A * * * Lot 945 Exp. Date May 1963 * * * Nitrofurantoin (F+) 100 Mcg Sulfisoxazole (G+) 300 Mcg Kanamycin (K+) 30 Mcg Methenamine Mandelate (M+) 2.5 Mg. Neomycin (N+) 30 Mcg Polymyxin B (PB+) 300 Units Dihydrostreptomycin (S+) 30 Mcg Vancomycin (VA+) 30 Mcg," and "Mfg. by Consolidated Laboratories, Inc., Chicago Heights, Illinois * * * For use in laboratory diagnosis only to determine microbial sensitivity to antibiotics, sulfonamides, and other chemotherapeutic agents."

RESULTS OF INVESTIGATION: Analysis shows that the percent of potency of the erythromycin, oleandomycin, oxytetracycline, and tetracycline in the Code No. 11-83D was in excess of 150 percent, which exceeds the standard as set forth in the Antibiotic Regulations.

LIBELED: 8-15-62, E. Dist. N.Y.

CHARGE: Code No. 11-S3D, 501(c)—when shipped, its strength differed from that which it was purported to possess.

Discs of both codes, 502(1)—when shipped, the articles were represented as drugs composed wholly or in part of a kind of penicillin, streptomycin, Aureomycin (chlortetracycline), chloramphenicol, or bacitracin, or any derivative thereof, and they were not from a batch with respect to which a certificate or release was in effect pursuant to 507.

DISPOSITION: 7-30-63. Default—destruction.

DRUGS FOR VETERINARY USE

7687. Medicated feeds. (Inj. No. 441.)

COMPLAINT FOR INJUNCTION FILED: 12-17-62, N. Dist. N.Y., against Ogden Grain Co., Inc., a corporation, Utica, N.Y.

CHARGE: The complaint alleged that the defendant was engaged in the business of manufacturing, preparing, packing, selling, introducing and causing to be introduced, and delivering and causing to be delivered for introduction into interstate commerce, articles of drug (*medicated feeds*) which were adulterated and misbranded; that the defendant was doing certain acts which resulted in the adulteration and misbranding of articles of drug which were held for sale by the defendant after shipment in interstate commerce; and that the articles of drug, when shipped and while held for sale after shipment, as above, were adulterated and misbranded as follows:

(a) a number of the articles were adulterated within the meaning of 501(c), in that they were not subject to 501(b), and their strength differed from that which they purported and were represented to possess;

(b) a number of the articles were misbranded within the meaning of 502(e)(2) in that they were not designated solely by names recognized in an official compendium and were fabricated from two or more ingredients and the labels failed to bear the common or usual name of the active ingredient;

(c) a number of the articles were misbranded within the meaning of 502(f)(1) in that the labeling failed to bear adequate directions for use;

(d) a number of the articles were misbranded within the meaning of 502(1) in that they contained a certifiable antibiotic for which no certificate or release was issued under 507 or for which no certificate or release was in effect.

The complaint alleged further that the adulterated and misbranded conditions of the articles of drug resulted from deficiencies in the ingredients of the articles, or the presence in the articles of ingredients in excess of the amounts declared or represented to be present, which were due to inadequate manufacturing facilities, lack of ingredient and product identification, lack of production controls, lack of adequate analysis and formulas, or lack of other precautions essential to the manufacture and preparation of such drugs, or, in the case of feed products containing antibiotics, failure to process certificates or release therefor, issued pursuant to Section 507, or noncompliance with conditions for exemption from the requirement of such certification; for example, the *Davis No. 5 Layer Pellets* were declared to contain 100 grams of chlortetracycline, but upon analysis contained only 50.9 grams; the *Ogden Hi-Energy Laying Mash Medicated* was declared to contain .01% of arsanilic acid, but contained from .00552% to .0116% in different batches (deficiencies from 44.8% to excesses of 16%); the *Ogden Big "O" Hi-Energy Laying Mash Medicated* had no declaration of arsanilic acid, but was found

to contain .00744%, .00698%, .00680%, and .00616% of that drug in different batches; *Complete Chick Starter with Trithiadol* was shipped notwithstanding suspension of antibiotic certificates of release; and Ogden products, on different occasions and as the result of separate analyses, had been found to have the following variances; sulfaquinoxaline, declared to be .0175% on the label, was found to be from 14.3% to 17.7% deficient in actual content; nicarbazin, declared to be .0125% on the label, contained only .0008%.

The complaint alleged also that the defendant was well aware that its activities were violative of the Act; that inspections of the defendant's plant at Utica, N.Y., were made by inspectors of the Federal Food and Drug Administration on September 30, 1959, November 16 and 17, 1960, and April 24, 1962; that on each occasion, the defendant was informed of inadequacies in its control system for the manufacture of its medicated feeds; that the defendant had been further warned by citations of its medicated feeds in August 1960 and May 1961, by hearings pursuant to Section 305, by the filing of a criminal prosecution against this defendant and its president and manager on May 7, 1962, and by suspension of exemption granted to the defendant pursuant to Sections 502(1) and 507(c) and regulations issued thereunder, authorizing the defendant to manufacture certain feeds containing antibiotics and drugs; that in addition, during the years 1959, 1961, and 1962, more than eight reports of improper and violative samples of the defendant's medicated feeds were made by regulatory agencies in the States of Connecticut and Massachusetts; that despite the warnings conveyed to the defendant by the aforesaid establishment inspections, seizures, hearings, reports of violation, and criminal prosecution, the defendant continued to introduce and cause to be introduced, and deliver and cause to be delivered for introduction into interstate commerce, articles of drug which were adulterated and misbranded as above; and that, despite such warnings, the defendant continued to do certain acts, while the articles of drug were held for sale after shipment in interstate commerce, which resulted in the articles of drug being adulterated and misbranded.

DISPOSITION: 12-17-62. The defendant having consented, the court entered a decree of permanent injunction enjoining and restraining the defendant as follows:

1. From shipping into interstate commerce, any articles of food or drug or any of its feed products which are adulterated or misbranded within the meaning of 501(c), 502(e) (2), 502(f) (1), or 502(1), because of deficiency or excess in the amounts of declared ingredients, inadequate manufacturing facilities, lack of adequate identification and production controls, lack of adequate analyses and formulas, or lack of other precautions essential to the manufacture and preparation of such articles or products, or, in the case of feed products containing antibiotics, failure to process certificates or release therefor, issued pursuant to Section 507 or noncompliance with conditions for exemption from the requirement of such certification;

2. From doing any act with respect to any articles of food or drug while such articles are held for sale after shipment in interstate commerce, which act results in any such article being misbranded or adulterated within the meaning of 501(c), 502(e) (2), or 502(f) (1), because of deficiency or excess in the amounts of declared ingredients, inadequate manufacturing facilities, lack of adequate identification and production controls, lack of adequate analyses and formulas, or lack of other precautions essential to the manufacture and preparation of such articles, or, in the case of feed products containing antibiotics, failure to process certificates or release therefor, issued pursuant to Section

507 or noncompliance with conditions for exemption from the requirement of such certification;

3. From preparing, shipping, selling, or delivering any of its feed products unless and until it has first set aside completely and held in isolation from all other ingredients and products in its plant, all drugs, medications, and antibiotics, and unless and until it has thoroughly cleaned all mixing and manufacturing equipment in its plant in order to eliminate all traces of drugs, medications, or antibiotics in such equipment, after which it may prepare, ship, sell, and deliver nonmedicated feed products;

4. From shipping into interstate commerce, any of its medicated feed products and from doing any acts with respect to any drug or medicated feed product while it is held for sale after shipment in interstate commerce, unless and until (a) adequate manufacturing facilities, adequate ingredient and product identification and controls, adequate product analyses and formulas, and other precautions essential to the manufacture and preparation of wholesome and lawful medicated feed products are installed in its plant; (b) adequate facilities, controls, and precautions are established in its plant to insure that its feed products which are not declared to contain drugs, medication, or antibiotics do not in fact contain any such drugs, medication, or antibiotics, that its feed products which are declared to contain drugs, medication, protein, or antibiotics do in fact contain the specified amounts of such drugs, medication, protein, or antibiotics, and that its feed products which contain any antibiotics possess certificates or releases therefor, issued pursuant to 507 or comply with conditions for exemption from the requirements for such certification; and (c) the Food and Drug Administration is notified that the defendant has undertaken and completed such improvements in its plant to insure the production of wholesome, lawful, unadulterated, and properly labeled feed products, and the defendant's plant has been inspected to verify that the improvements have been accomplished and a report of the inspection and satisfactory improvements in the defendant's plant have been made to the court.

7688. Procaine penicillin G suspension. (F.D.C. No. 47929. S. Nos. 75-421/5 T.)

QUANTITY: 4,347 individually ctn'd. vials at Modesto, Calif.

SHIPPED: Prior to 8-7-62, the penicillin ingredient of the article had been shipped from outside the State of California.

LABEL IN PART: (Ctn.) "UVC * * * Pen-AQ Sterile Procaine Penicillin G Suspension, U.S.P. 300,000 Units per cc. with 2% Procaine HCl, U.S.P. 100 cc. Multiple Dose Sterile Vial For Veterinary Use Only Distributed by United Veterinary Corporation, Des Moines, Iowa * * * For Intramuscular Injection Only * * * Store at 35° to 50° F."

RESULTS OF INVESTIGATION: The article was manufactured by Maurry Biological Co., Inc., Los Angeles, Calif., from penicillin shipped as described above. Analysis showed that the penicillin potency of a portion of the article met the potency requirement of the United States Pharmacopeia which requires 90 percent of the labeled potency, and that other portions of the article contained a penicillin potency ranging from 70.0 percent to 86.6 percent. Certain portions also failed to meet the standards for syringability as contained in the Antibiotic Regulations. All portions of the article bore outdated expiration dates and were stored by the dealer, Diamond Laboratories (formerly United

Veterinary Corp.), Modesto, Calif., at ordinary room temperature which was contrary to the storage directions on the label and to the requirement of the Antibiotic Regulations.

LIBELED: 8-7-62, N. Dist. Calif.

CHARGE: 501(b)—while held for sale, the strength of the article (except for 1 portion) differed from and its quality fell below the standard for Sterile Procaine Penicillin G Suspension, set forth in the United States Pharmacopeia; 502(a)—the labeling was false and misleading since it represented and suggested that the article complied with the standard for Sterile Procaine Penicillin G Suspension whereas the article (except for 1 portion) failed to meet such standard as to strength and quality and the article (all portions) failed to conform to the Antibiotic Regulations as required by the standard; and 502(1)—the article was composed wholly or in part of penicillin and it was from a batch with respect to which a certificate had been issued, which certificate had ceased to be effective since the packages of the article (all portions) bore an outdated expiration date and the article (except for 1 portion) failed to meet the standards for strength and quality which were in effect on the date of certification.

DISPOSITION: 3-11-63. Default—destruction.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

7689. Dextro-amphetamine sulfate capsules, secobarbital sodium capsules, meprobamate tablets, imitation Diuril tablets, and imitation Hydrodiuril tablets. (F.D.C. No. 47320. S. Nos. 59-273 R, 59-275 R, 59-308/9 R, 59-312 R, 13-162 T.)

INFORMATION FILED: 2-14-63, N. Dist. Ill., against Treiman Drugs, Inc., t/a Fifth Avenue Pharmacy, Chicago, Ill., Louis L. Treiman, president of the corporation, and Henry S. Papak, apprentice pharmacist.

ALLEGED VIOLATIONS: Between 4-13-61 and 9-6-61, while the following drugs were being held for sale after shipment in interstate commerce, *meprobamate tablets* were dispensed twice and *dextro-amphetamine sulfate capsules* and *secobarbital sodium capsules* were each dispensed once without a prescription, which acts resulted in such drugs being misbranded.

In addition, between 6-9-61 and 6-14-61, *imitation Diuril tablets* and *imitation Hydrodiuril tablets* were offered for sale and sold in filling prescriptions for Diuril and Hydrodiuril, respectively, which acts were done while the drugs were held for sale after shipment in interstate commerce, and resulted in the drugs being adulterated.

CHARGE: *Imitation Diuril tablets* and *imitation Hydrodiuril tablets*, 501(d) (2)—while held for sale, the imitation articles had been substituted for Diuril tablets and Hydrodiuril tablets.

Meprobamate tablets, *dextro-amphetamine sulfate capsules*, and *secobarbital sodium capsules*, 503(b) (1)—while held for sale, the articles were dispensed without a prescription.

PLEA: Nolo contendere by the corporation to the counts involving the *secobarbital sodium capsules* and the imitation drugs; by Louis Treiman to the counts involving the imitation drugs and to one count involving the *meprobamate tablets*; and by Henry Papak to the counts involving the *dextro-amphetamine sulfate capsules* and *secobarbital sodium capsules* and one count involving the *meprobamate tablets*.

DISPOSITION: The defendants filed a motion to dismiss the information and a motion for a bill of particulars. On 4-26-63, the court handed down the following opinion with respect to such motions:

PARSONS, *District Judge*:

MEMORANDUM OPINION AND ORDER

"I have before me two motions: (1) a motion to dismiss the information; and (2) a motion for a bill of particulars.

"Defendants' motion to dismiss primarily is based on the contention that 21 USCA § 353 is so vague, indefinite and uncertain as to deny due process of law. Were this a matter of first impression, I might be more sympathetic to this position. But I think the argument has been adequately disposed of by our Seventh Circuit in the case of *United States v. 2600 State Drugs, Inc.*, 235 F. 2d 913.

"In answer to defendants' other contentions, I think it hardly can be said that one is not put on notice that he may be committing a crime, when the bottles in which the drugs were shipped were labeled in part as follows: 'Caution: Federal law prohibits dispensing without prescription.' Furthermore, compliance with Section 335 requiring the Secretary, before reporting a violation for prosecution, to give the suspect an opportunity to present his views, is not a prerequisite to prosecution. *United States v. Dotterweich*, 320 U.S. 277. And, finally, the question of whether the drugs were shipped in interstate commerce may be argued at the time of trial, but since the necessary allegations have been made nothing more is required at this time.

"Accordingly, defendants' motion to dismiss is denied.

"Insofar as defendants' motion for a bill of particulars is concerned, however, I am differently disposed. I think defendants should be informed as to the ingredients of the capsules, the meaning that may be placed on the words 'that prior to . . .', the names of the physicians who wrote the prescriptions which were filled by the defendants, and the quantity of drugs dispensed in violation of law. The specific provisions of 21 USC § 353(b) (1) which are being relied on by the Government are sufficiently set out.

"Accordingly, defendants' requests Numbered 1, 2, 3 and 4 are allowed, but request Numbered 5 is denied."

On 6-21-63, the court fined the corporation \$300, plus costs, and each individual \$105, plus costs.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

7690. Various prescription drugs. (F.D.C. No. 47686. S. Nos. 12-846/56 T.)

QUANTITY: Approximately 200 pkgs. and btls. of drugs at Des Plaines, Ill., in possession of Hynes Pharmacy.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Complimentary," "Physician's Sample," "Professional Sample," "Sample Not To Be Sold," "Physician's Trial Package," and "Clinical Trial Supply."

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked from physicians' samples into containers having labels bearing brand names indicative of manufacture outside the State of Illinois and (some labels) the words "Complimentary," "Physician's Sample," "Professional Sample," or similar wording, and (some labels) the names and addresses of manufacturers, packers, or distributors located outside the State of Illinois.

The articles also consisted of quantities of prescription drugs which were not yet repacked, originally intended for use as samples, and still in the

*See also No. 7682.

original sample packages bearing the names and addresses of manufacturers, packers, or distributors located outside the State of Illinois.

LIBELED: 6-21-62, N. Dist. Ill.

CHARGE: 502(a)—while held for sale, the sample legends on the labels of a number of the articles were false and misleading as applied to articles then in the possession of a repacker and intended for sale and not then intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b) (1)—a number of the repacked articles of drug failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(e) (2)—the labels of a number of the repacked articles failed to bear the common or usual name of each active ingredient contained therein; 502(f) (1)—the labeling of a number of the repacked articles failed to bear adequate directions for use and they were not exempt from that requirement since they were subject to the provisions of 503(b) (1), and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the articles as required by regulations; and 503(b) (4)—a number of the repacked articles were subject to the provisions of 503(b) (1), and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 8-2-62. Default—destruction.

7691. Various prescription drugs. (F.D.C. No. 47901. S. Nos. 54-890/8 T.)

QUANTITY: 4,188 tablets and capsules at Palatka, Fla., in possession of Professional Pharmacy #2.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: "Professional Sample," "Trial Package," "Sample," or similar wording.

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked from physicians' samples into containers having labels bearing brand names indicative of manufacture outside the State of Florida, and the words "Professional Sample," "Professional Trial Package," "Sample," or similar wording and (some labels) the names and addresses of manufacturers, packers, or distributors outside the State of Florida.

LIBELED: 7-26-62, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the statements "Professional Samples," "Professional Trial Package," "Sample," and similar wording on the labels of a number of the articles were false and misleading as applied to the articles which were in the possession of a repacker and intended for sale, and not intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b) (1)—a number of the articles failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(e) (2)—a number of the articles were drugs not designated solely by a name recognized in an official compendium and they were fabricated from two or more ingredients and their labels failed to bear the common or usual name of each active ingredient contained therein; 502(f) (1)—the labeling of a number of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were subject to the provisions of 503(b) (1), and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history as is required

by regulations; and 503(b) (4)—a number of the articles were subject to the provisions of 503(b) (1), and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 11-19-62. Default—destruction.

7692. Various drugs. (F.D.C. No. 46641. Inj. No. 438. S. Nos. 94-442/4 R, 94-481/4 R, 94-486/92 R.)

QUANTITY: 1 10,000-tablet drum of *Special Formula No. 3212*; 1 10,000-tablet drum of *Special Formula No. 3210*; 1 30,000-tablet drum of *Special Formula No. 3211*; 11 cases, 24 90-tablet btl. each, of *Foodine*; 21 cases, 42 90-tablet btl. each, of *Calcium from Egg Shells*; 1 270-tablet btl. of *Soy-Hi Protein*; 19 cases, 24 1¾-oz. btl. each, of *Vegetable Seasoning*; 5 cases, 72 100-tablet btl. each, 1 box containing 12 30-tablet btl., and 14 cases, 24 100-tablet btl. each, of *Multi-Vitamins*; 2 boxes, 12 60-tablet btl. each, 1 case containing 72 90-tablet btl., and 2 cases, 72 60-tablet btl. each, of *vitamin C*; 2 cases, 48 60-tablet btl. each, of *Herb Laxative*; 1 case containing 72 100-tablet btl. of *Carminative Digestant Aid*; 1 case containing 72 90-capsule btl. of *vitamin E*; 2 cases, 48 60-tablet btl. each, of *vitamin A*; and 114 2-oz. btl. in oil form and 28 2-oz. jars in cream form of *Special Purpose Oils*, at Detroit, Mich., stored for the account of Dr. William L. Abt.

SHIPPED: The *Special Formula tablets* were shipped between 5-15-61 and 6-6-61, from St. Louis, Mo.; the *Foodine tablets* were shipped on 5-17-61, from Los Angeles, Calif., and repacked into bottles at Oak Park, Mich.; the *Multi-Vitamin tablets* were manufactured at Oak Park, Mich., from raw materials shipped from outside the State of Michigan, and were packaged and delivered to Dr. Abt between 5-10-61 and 5-23-61; and the other articles were shipped between 5-15-61 and 6-10-61, from Los Angeles, Calif., and Buffalo, N.Y.

LABEL IN PART: (Drum) "Special Formula No. 3212 [or "3210" or "3211"] For Dr. W. L. Abt, Dearborn, Mich."; (btl.) "Abt's (Natural) Foodine (90 Tablets) A concentrated Dietary Supplement Rich in Organically Bound Iodine * * * Abtco Distributors, 12718 W. Warren Dearborn, Michigan TH3987," "90 Tablets Calcium From Egg Shells 3 Tablets Contains * * * Abtco Distributors Los Angeles, California * * * 8179," "270 Tablets Soy-Hi Protein Nutritious Body Building Supplement Made Expressly for Abtco Distributors Los Angeles, California * * *," "Abtco Organic Products A Vegetable Seasoning Contents: 1¾ Ozs. Contents: * * * Abtco Distributors * * * Los Angeles 46, Calif. * * * 9198 * * *," "Abt's Multi-Vitamin Each 4 tablets contain: * * * Abtco Distributors * * * Dearborn, Michigan * * *," "Natural Organic Vitamin C Abtco Organic Products Each Tablet Contains: * * * Distributed By: Abtco Distributors * * * Dearborn, Michigan * * *," "60 Tablets Abtco Herb Laxative Tablets Ingredients: * * * Abtco Distributors * * * Hollywood 46, California * * * 9449 * * * Warning * * *," "100 Tablets Abtco Carminative Digestant Aid Activated Charcoal (Willow) U.S.P., Papain, Malt Diastase and Oil of Peppermint (Natural) * * * Distributed by: Abtco Distributors * * * Hollywood 46, California 7589," "90 Capsules Vitamin E * * * Each Capsule Contains: * * * Directions: * * * Distributed by: Abtco Distributors * * * Hollywood 46, Calif. 7023," "Abtco Organic Products Vitamin A Each Tablet Contains: 5,000 U.S.P. Units * * * 60 tablets Distributed by Abtco * * * Los Angeles, Calif. * * * 9729 * * *," and "All Natural Formula Special Purpose Oils * * * 2 Fl. Oz. Specially prepared for Abtco Santa Ana, California."

LIBELED: 12-6-61, E. Dist. Mich.

CHARGE: 502(f) (1)—the labeling of the articles (except for Formulas 3210, 3211, and 3212) failed to bear adequate directions for use for the purposes for which they were intended, namely: *Foodine tablets*—in the treatment and prevention of thyroid disturbance, fatigue, overweight condition, improper functioning of the parathyroid gland, and improper metabolism; *Calcium From Egg Shells*—for the treatment and prevention of improper growth of bones; improper functioning of bone marrow, bones, thyroid, and parathyroid glands; improper pH of the blood; longevity; and lack of strength and firmness of the arteries; *Soy-Hi Protein*—in the treatment and prevention of poor health, shortened life, ulcers, cancer, poisons and infections of the body, sterility, improper growth and regeneration of hemoglobin, and liver and gallbladder conditions; *Vegetable Seasoning*—in the treatment and prevention of hardening of the arteries, arthritis, and poor eyesight and hearing; *Multi-Vitamins*—in the treatment and prevention of degeneration of the body, pyorrhea, stomach ulcer, gallstones, diabetes, poor eyesight, bacterial infection, corneal ulcers, glaucoma, kidney and bladder troubles, sexual impotency, and heart failure; *vitamin C*—in the treatment and prevention of degeneration of the body, bleeding gums, pyorrhea, intestinal bleeding, stomach ulcer, constipation, gallstones, asthma, allergies, and diabetes; *Herb Laxative tablets*—in the treatment and prevention of piles, hemorrhoids, abnormal functioning of veins, bad breath, tumors, gallbladder condition, pathological functioning of organs of the body, aches and pains, improper eyesight, and poor memory; *Carminative Digestant Aid*—in the treatment and prevention of fermentation; conditions of the ears, eyes, brain, and motor nerves; jaundice; and unclean blood; *vitamin E*—in the treatment and prevention of poor health, liver and gallbladder conditions, male impotency, heart failure, aging skin, and kidney condition; *vitamin A*—in the treatment and prevention of cataracts, hardness of hearing, blood vessels breaking in the brain, poor eyesight, ulceration, constipation, and glaucoma; and *Special Purpose Oils*—in the treatment and prevention of wrinkles, baggy skin, fungus infection, split tongue, improper skin development, and aging skin; which were the diseases, conditions, and purposes for which the articles were offered in oral statements made by Dr. William L. Abt during a series of lectures at Detroit, Mich., during the periods of June 6 through June 9, 1961, and of June 12 through June 15, 1961; and by references made by Dr. William L. Abt during the lectures, to a book entitled "The Key To Good Health and Longevity by Dr. W. L. Abt."

Formula 3210, 502(f) (1)—when shipped, the labeling failed to bear adequate directions for use since the conditions for its use were not stated; and 502 (f) (2)—the article was a laxative, and its labeling failed to warn that the article should not be used when abdominal pain, nausea, or vomiting were present and that its frequent or prolonged use may result in dependence on laxatives.

Formulas 3211 and 3212, 503(b) (4)—when shipped, the articles were not subject to 503(b) (1), and their labels bore the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 9-21-62. W. L. Abt, claimant, having consented to the entry of a decree, judgment was entered providing for the condemnation and destruction of the articles and ordering that the claimant cease and desist from the future manufacture or sale of any food supplements, as set forth in the libel, or any similar food supplements.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS**DRUGS AND DEVICES FOR HUMAN USE***

7693. Nutri-Bio food supplement. (F.D.C. No. 47178. S. Nos. 10-078 T, 10-668 T.)

QUANTITY: 118 units, at Tonawanda, N.Y., in possession of Louis Kiss, each unit consisting of 2 ctns. enclosed in a cardboard sleeve, each ctn. containing 13 plastic envelopes of 14 tablets and 28 tablets each.

SHIPPED: 11-27-61, from Elk Grove Village, Ill., by Nutri-Bio Corp.

LABEL IN PART: (Ctn.) "Nutri-Bio (better NUTRition thru BIOchemistry) Dietary Food Supplement Vitamin and Mineral Tablets 364 Mineral Tablets 182 Vitamin Tablets * * * from natural food sources * * * Available only through Authorized Nutri-Bio Distributors * * * Formulated for and Distributed by Nutri-Bio Corporation, 291 S. La Cienega Blvd. Beverly Hills, California," (sleeve) "Nutri-Bio dietary food supplement * * * the Nutri-Pak * * * Pocket carrier * * * contains a 7-day adult supply of Nutri-Bio. This package contains 26 Nutri-Paks. * * * Nutri-Bio Corporation," and (envelope) "Your Seven-Day Supply of Nutri-Bio dietary food supplement natural or organic Vitamins & Minerals for the entire family. Formulated for and distributed by Nutri-Bio."

ACCOMPANYING LABELING: Folders entitled "Do you know," "The Nutri-Bio Program For Better Living," and "Baby-Bio by Nutri-Bio," and a film entitled "Just to be sure."

LIBELED: 3-6-62, W. Dist. N.Y.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective to promote mental and physical health, zest, radiant living, being alert and pleasant, promote happiness, sociability, enthusiasm, liveliness, vigor, and awareness; that the article was of significant value for special dietary supplementation and therapeutic use by reason of the presence of unsaturated fatty acids, inositol, para-aminobenzoic acid, rutin, biotin, bioflavonoid complex, hesperidin complex, choline, alfalfa juice and powder concentrate, potassium, sulfur, choline, copper, zinc, manganese, magnesium, and montmorillonite; that the article was a complete and balanced vitamin and mineral food supplement; that everyone needs food supplements; and that the article was of special significance for special dietary supplementation and therapeutic use because the ingredients were of natural or organic origin; and 502(f) (1)—while held for sale, the labeling failed to bear adequate directions for use in the treatment and prevention of psoriasis, colds, lack of pep, bursitis, arthritis, lack of appetite, measles, tiredness, overweight and underweight conditions, bad teeth, and to cause a person to sleep and feel better; which were the conditions and purposes for which the article was offered in oral statements made by Louis Kiss, Nutri-Bio sales agent, in a sales talk at Buffalo, N.Y.

DISPOSITION: 12-11-62. Default—destruction.

7694. Larson's C.R.D. food supplement. (F.D.C. No. 47561. Inj. No. 448. S. Nos. 23-376/7 T.)

QUANTITY: 12 cases, each containing 12 7½-oz. btl., at Denver, Colo., in possession of Walgreen Drug Stores.

*See also Nos. 7681, 7682, 7690-7692.

SHIPPED: 2-9-62 and 3-15-62, from Chicago, Ill., by Fleetwood Co.

LABEL IN PART: (Btl.) "Larson's C.R.D. A Dietary Food Supplement To Be Mixed In Coffee or Tea Each Ounce (4 Heaping Teaspoonfuls) Contains: 4000 U.S.P. Units Vitamin A * * * 400 U.S.P. Units Vitamin D * * * Gelatin, Dextrose * * * Distributed by Fleetwood Company-Chicago-Toronto How To Take * * * Larson's C.R.D. Reducing Diet Plan (For Complete Plan Read Booklet Inside Package)."

ACCOMPANYING LABELING: Leaflet entitled "Larson's C.R.D. Reducing Diet Plan"; and counter display sheet reading in part "Overweight? New 8 Hour Diet Takes Pounds and Inches Excess Fat Off Big Eaters! * * * Get Larson's C.R.D. Today * * * At All Walgreen Drug Stores."

RESULTS OF INVESTIGATION: Investigation showed that the counter display sheet was a clipping of an advertisement which appeared on 3-19-62, in a local newspaper. The mat of this advertisement was prepared on order of the Fleetwood Co., Chicago, Ill. The advertisement was paid for by the Walgreen Drug Company's main office at Chicago, Ill. The information indicated that the mat for the advertisement was sent by Walgreen Drug Co., Chicago, Ill., to its branch store at Denver, Colo., and the latter then placed the advertisement with a local newspaper.

LIBELED: 5-2-62, Dist. Colo.

CHARGE: 502(a)—when shipped and while held for sale, the counter display sheet contained false and misleading representations that the article was a reducing diet; that it was adequate and effective to take pounds and inches of excess fat off big eaters in 8 hours by dieting one meal a day while eating everything during breakfast and dinner just as normally eaten, and without counting calories; to melt away fat from all parts of the body while eliminating thousands of calories daily; to promote energy; and to prevent tiredness and listlessness; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use of the article for all conditions and purposes for which it was intended and prescribed, recommended, and suggested, in the counter display sheet reading in part "Overweight? New 8 Hour Diet Takes Pounds and Inches Excess Fat Off Big Eaters! * * * Get Larson's C.R.D. Today * * * At all Walgreen Drug Stores."

DISPOSITION: 11-15-62. Consent—claimed by Fleetwood Co., Chicago, Ill., and brought into compliance with the law. The consent decree also permanently enjoined the claimant from:

(1) Introducing into interstate commerce, the drug, "*Larson's C.R.D.*," or the same drug by any other designation, or any similar drug, which is misbranded within the meaning of 502(a) by reason of the inclusion in its labeling of any false and misleading statements which represent and suggest that the drug is a reducing diet; that it is adequate and effective to take pounds and inches of excess fat off big eaters in eight hours by dieting one meal a day while eating everything during breakfast and dinner just as normally eaten, and without counting calories; to melt away fat from all parts of the body while eliminating thousands of calories daily; to promote energy; and to prevent tiredness and listlessness; or

(2) Doing or causing to be done, any act with respect to the drug, "*Larson's C.R.D.*," or the same drug by any other designation, or any similar drug, while such drug is held for sale after shipment in interstate commerce, which results

in such drug being misbranded within the meaning of 502(a) by reason of the inclusion in its labeling of the false and misleading statements described above; or

(3) Introducing into interstate commerce, the drug, "*Larson's C.R.D.*," or the same drug by any other designation, or any similar drug, which is misbranded within the meaning of 502(f) (1) in that its labeling fails to state each and every purpose, disease, and condition for which such drug is offered together with sufficient information to enable the layman to medicate himself safely and effectively with the drug for each such purpose, disease, and condition; or

(4) Doing or causing to be done, any act with respect to the drug, "*Larson's C.R.D.*," or the same drug by any other designation, or any similar drug, while such drug is held for sale after shipment in interstate commerce, which results in such drug being misbranded within the meaning of 502(f) (1) in the manner described above.

7695. Rysal tablets. (F.D.C. No. 48210. S. No. 33-923 T.)

QUANTITY: 33 cases, each containing 12 100-tablet btl., at Minneapolis, Minn., in possession of Minnesota Pharmaceutical Laboratories, Inc.

SHIPPED: 10-24-60, from Seymour, Ind.

LABEL IN PART: (Btl.) "Rysal For relief from the symptoms of allergic rhinitis or the common cold. Each tablet contains: Salicylamide, (3½ gr.) 230 mg.; Acetophenetidin (2½ gr.) 150 mg.; Phenylephrine HCL, 5 mg.; Chlorpropfen Maleate, 2 mg.; Racephedrine HCL, 5 mg.; Caffeine, 30 mg. Adult dosage: Two tablets with a full glass of water when symptoms are first noted, and one or two tablets every four hours as needed to provide relief. Caution: * * * Manufactured for Minnesota Pharmaceutical Laboratories, Inc., Minneapolis, Minnesota."

RESULTS OF INVESTIGATION: The article was shipped in bulk drums and packaged locally on order of the dealer.

LIBELED: 10-3-62, Dist. Minn.

CHARGE: 502(f) (1)—while held for sale, the labeling of the article failed to bear adequate directions for use in that the recommended dosage was excessive; and 502(f) (2)—the labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users.

DISPOSITION: 11-14-62. Consent—claimed by the dealer and released under bond for relabeling.

7696. Lipo-Cylate solution. (F.D.C. No. 47179. S. No. 1-357 T.)

QUANTITY: 33 cases, each containing 6 16-oz. btl., at Columbia, S.C., in possession of Palmedico, Inc.

SHIPPED: 10-21-61, from St. Louis, Mo., by Donley-Evans & Co.

LABEL IN PART: (Btl.) "Lipo-Cylate * * * Twice A Day Dosage Sodium Salicylate Each teaspoonful (5 cc.) provides 500 mgm. approximately (7½ grains) of sodium salicylate * * * Distributed by Palmedico, Inc. * * * Columbia, S.C."

RESULTS OF INVESTIGATION: The labels for the article were prepared by the dealer and supplied to the manufacturer.

LIBELED: 3-2-62, E. Dist. S.C.

CHARGE: 502(f) (1)—when shipped, the labeling of the article failed to bear adequate directions for use for the purposes and conditions for which it was intended, namely, for use by the laity as an analgesic, antipyretic, and anti-rheumatic of benefit in the management of arthritic and rheumatic conditions, since adequate directions for such use cannot be written for the laity; 502(f) (1)—its labeling failed to bear adequate directions for use in that the directions on the label for the use of the article by the physician in acute anti-rheumatic conditions were not adequate since there are no conditions by the name of "acute antirheumatic conditions" which are known to exist; 502(f) (1)—its labeling failed to bear adequate directions for use in that its labeling contained statements recommending the use of the article by children and the labeling failed to bear adequate dosage directions for use by children; and 502(f) (2)—the article was recommended for use in arthritis and rheumatism and its labeling failed to bear a statement warning that if pain persists for 10 days, or if redness is present, or in conditions affecting children under 12 years of age, that a physician should be consulted.

DISPOSITION: 11-14-62. Consent—claimed by Palmedico, Inc., Columbia, S.C., and relabeled.

7697. Filter Queen vacuum cleaner and accessory devices and attachments.
(F.D.C. No. 48833. Inj. No. 479. S. No. 21-879 V.)

QUANTITY: 225 vacuum cleaners, 225 boxes of attachments, 77 vibrator accessory devices, and 28 demother accessory devices, at Denver, Colo., in possession of Filter Queen, Inc.

SHIPPED: Between 2-14-63 and 3-22-63, from Chicago, Ill., by Health-Mor, Inc.

LABEL IN PART: (Vacuum cleaner) "Filter Queen Health-Mor, Inc. Chicago, Ill. Serial * * * Model 33"; (vibrator) "Filter Queen Vibrator"; (demother) "Filter Queen Jet De-Mother."

ACCOMPANYING LABELING: Pamphlets entitled "How to Demonstrate the Filter Queen," "Know The Truth About 'Vacuum Cleaners'," "Filter Queen Home Sanitation System," and "Here is the Inside Story * * *"; booklets entitled "Filter Queen Home Sanitation System" and "Sales Aid Information"; leaflets entitled "One of the most important developments in home sanitation in 50 years"; reprint entitled "Filth In The Air: * * *"; and sheets entitled "There is Dust, Dirt and Filth in the air * * *," "NOTICE Dust and Disease * * *," "WARNING * * * Smallpox Scarlet Fever Measles Pleurisy * * *," "Smog Control Urged in Fight on Cancer * * *," "* * * This Vacuum Cleaner Filters Dust From Air * * *," "* * * Air Pollution Kills 700 in Chicago * * *," "House Dust Allergy * * *," "Letter from Doctors General Hospital, San Jose, California," "MORE PROOF that Filter Queen is truly FOR YOUR HEALTH'S Sake! * * *," and "Filter Queen Wins Law Suit Against Lewyt * * *."

RESULTS OF INVESTIGATION: Examination indicated the article to be similar to conventional canister-type vacuum cleaners with attachments, including a portable vibrator unit attachment.

LIBELED: 4-3-63, Dist. Colo.

CHARGE: 502(a)—when shipped, the carton label of the vibrator accessory contained false and misleading representations that the articles were adequate

and effective as a treatment for relieving muscular pain and discomfort from arthritis and rheumatism; aiding health; firming flesh; and reducing unwanted fat; and 502(f)(1)—while held for sale, the labeling of the articles failed to bear directions for use for improving one's health, and overcoming asthma, hay fever, arthritis, rheumatism, and sinus headache, which were the conditions and purposes for which the articles were offered in oral statements made by Herb Beasley, Filter Queen salesman, on 2-12-63.

DISPOSITION: 4-25-63. Consent—claimed by Filter Queen, Inc., of Denver, Colo., and ordered released for relabeling.

The consent decree of condemnation also permanently prohibited and enjoined Filter Queen, Inc., from doing, or causing to be done, any act, oral or otherwise, with respect to any of the seized devices which would result in any of such devices being offered for the purpose of overcoming asthma, hay fever, arthritis, rheumatism, and sinus headache, or for any similar medical purpose.

7698. Automatic and portable water softener devices and components. (F.D.C. No. 48970. S. Nos. 22-662/65 V, 23-689 V.)

QUANTITY: 75 automatic devices, 6 portable devices, 75 $\frac{3}{4}$ -cu. ft. bags of resin, and 200 100-lb. bags of salt, at Wheat Ridge and Denver, Colo., in possession of Lindsay Soft Water Co., Inc.

SHIPPED: Between 2-15-63 and 4-16-63, from St. Paul, Minn., Salt Lake City, Utah, and Gardena, Calif.

LABEL IN PART: (Automatic device) "The Lindsay Company * * * Automatic Water Softener"; (bag) "Lindex High Capacity Ion Exchange Resin * * * $\frac{3}{4}$ Cu. Ft."; and (bag) "100 Lbs. Net Weight Solar Lindsay Salt For use in Lindsay All-Automatic Water Softeners Extra Coarse Packed for The Lindsay Company."

ACCOMPANYING LABELING: Leaflets entitled "Care of the Body," "Hard Water is Factor in Cancer of Bladder," "Thirst is Best Satisfied * * *," "Doctors agree water is 84% of Life," "Medical Times," and "Danger in Your Drinking Water."

RESULTS OF INVESTIGATION: The automatic water softener was packaged in 2 cartons, one containing a "Brine Tank," and the other containing a "Mineral Tank" and a "time switch." Some of the accompanying labeling had been reprinted locally for the dealer firm. Examination indicated that the assembled *automatic water softener device* consisted of an outer fiber glass cylindrical tank containing an inner cylindrical fiber glass tank and an automatic electrical timing switch. The *portable water softener device* appeared to be similar in design and construction to the larger automatic devices. The resin and salt were components necessary for the proper operation of the devices.

LIBELED: 5-27-63, Dist. Colo.

CHARGE: 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the articles were adequate and effective as a treatment for and prevention of cancer, gout, rheumatism, kidney and stomach ailments, arteriosclerosis, radioactive poisoning, constipation and other medical conditions; and 502(f)(1)—the labeling of the articles failed to bear adequate directions for use for the prevention and treatment of arthritis, rheumatism, gallstones, kidney stones, colds, flu, polio, typhoid, diphtheria, diarrhea, stomach disorders, and other disease conditions for

which the articles were offered in oral statements made by Ray Darnaud, salesman for Lindsay Soft Water Co., Inc., Wheat Ridge, Colo.

DISPOSITION: 6-10-63. Consent—claimed by Lindsay Soft Water Co., Inc., Wheat Ridge, Colo., for relabeling.

The consent decree also provided that Lindsay Soft Water Co., Inc., and each and all of its present and future officers, agents, servants, employees, and independent contractors, were permanently prohibited and enjoined from doing, or causing to be done, any act, oral or otherwise, with respect to any of the seized devices, resin, and salt, and any similar devices and chemicals, under the same or other names, which would result in any of such devices and chemicals being offered for the purpose of treatment and prevention of cancer, gout, rheumatism, kidney and stomach ailments, kidney stones, colds, flu, polio, typhoid, diphtheria, diarrhea, or any other disease conditions or body ailments.

7699. Affinitizer device (2 seizure actions). (F.D.C. Nos. 48241, 48243. S. Nos. 78-967 T, 78-969 T.)

QUANTITY: 2 devices, at Elk Point and Tyndall, S. Dak.

SHIPPED: Between 1-1-51 and 12-31-53, from Orinda, Calif.

LABEL IN PART: "Seroyal Magnetic—Pendul Affinitizer."

RESULTS OF INVESTIGATION: The device appeared to be in the form of a hollow plastic block, about 12 inches square and 1 inch thick. On the face of the block was an indicator dial with inscribed numbers ranging from 0 to 270. The unit contained no electrical circuit, but the dial operation was reportedly magnetic. Three plastic strings were taped to the plastic block. For diagnostic purposes, one string was held over the area of the patient's heart, one string was placed in the area of the gland or organ to be checked, and one string was held over the dial of the device.

CHARGE: 502(b) (1)—while held for sale, the device failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and 502(f) (1)—the labeling failed to bear adequate directions for use for the purposes and conditions for which the device was intended, in that adequate directions could not be written since the device was worthless for any medical purpose.

DISPOSITION: 12-27-62. Default—destruction.

7700. Dr. Scholl's Foot Exercizer Sandals. (F.D.C. No. 49038. S. No. 23-101 X.)

QUANTITY: 46 ctns., each containing 1 pair of sandals, of various sizes for men and women, at Denver, Colo.

SHIPPED: Prior to and on or about 6-6-63 and 7-9-63, from Chicago, Ill., by Scholl Manufacturing Co., Inc.

LABEL IN PART: (Ctn.) "Dr. Scholl's Foot Exercizer Sandals * * * The Scholl Mfg. Co., Inc."

ACCOMPANYING LABELING: Leaflets in carton reading in part "Money Back Guarantee" and newspaper advertisement mats reading in part "Dr. Scholl's * * * Foot Exercizer * * * Amazing New Appliance Can Help Relieve Tired, Aching, Weak Feet * * * Flabby Foot And Leg Muscles * * * Varicose Veins And Other Common Foot Disorders."

RESULTS OF INVESTIGATION: Examination showed that the article consisted of a sandal-like wooden shoe, shaped to the contour of the foot with a buckle-type single strap and a crepe sole.

The newspaper mats were used to place an advertisement in a Denver newspaper, on 6-3-63.

LIBELED: 7-16-63, Dist. Colo.

CHARGE: 502(a)—when shipped and while held for sale, the newspaper mats contained false and misleading representations that the article was adequate and effective as a treatment for varicose veins, flabby foot and leg muscles, and to relieve tired, aching, weak feet; and 502(f) (1)—the labeling failed to bear adequate directions for use for the conditions for which the article was offered in the newspaper advertisement.

DISPOSITION: 8-13-63. Consent—claimed by J. and V. Toth, t/a Dr. Scholl's Foot Comfort Shop, Denver, Colo., and released under bond for relabeling.

7701. Vac-U-Prep device. (F.D.C. No. 48595. S. No. 19-099/ V.)

QUANTITY: 400 boxes, each containing 1 device, and the following component parts to complete the assembly of 2,365 devices, namely, 2,365 scoops with tube fitting, 2,365 scoops without tube fitting, 2,365 mouthpieces (in 2 parts), and 8,000 feet of clear plastic tubing, at Ada, Okla., in possession of Sooner Prosthetics, Inc.

SHIPPED: Between 11-1-61 and 11-10-62, component parts for the device were shipped from Fort Worth, Tex.

LABEL IN PART: (Box) "Vac-U-Prep."

ACCOMPANYING LABELING: Instruction sheets entitled "Vac-U-Prep * * * Directions * * *" and leaflets entitled "Medical Bulletin #1" and "A Scientific Answer to Male Impotence."

RESULTS OF INVESTIGATION: Examination showed that the device consisted of a 38.5-inch length of clear plastic tubing ($\frac{3}{16}$ -inch overall diameter), one end of which was connected to a white, hard plastic scoop-shaped unit, $4\frac{1}{8}$ inches long by $1\frac{3}{16}$ inches across. This unit appeared to be hollow, since it was about $\frac{3}{16}$ inches thick at the center and had 3 holes on the inside part of the scoop, 1 hole on the outside part, and 1 hole on the end opposite the tubing connection. The other end of the tubing was connected to a cylindrical-shaped tube of white, hard plastic drawn out to a tubing connection on one end and to a mouthpiece-shape on the other end. The fourth part was a scoop-shaped unit identical to the one described above except that it had no tubing connection. The accompanying labeling was printed locally on order of the dealer.

LIBELED: 1-9-63, E. Dist. Okla.; amended libel 4-23-63.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the device was an adequate and effective treatment for senile impotence of a psychological nature, premature senility, lessened flow of blood due to circulatory difficulties, premature ejaculation and marital sexual incompatibility; and 502(f) (1)—the labeling failed to bear adequate directions for the unsupervised use, by the laity, of the device for self-diagnosed conditions such as male impotency and premature ejaculation, in that adequate directions for such unsupervised use by the laity cannot be written.

DISPOSITION: 7-5-63. Consent—destruction.

7702. Micro-Dynameter devices. (F.D.C. No. 48302. S. Nos. 10-122/5 T, 92-560 T.)

QUANTITY: 5 devices, at McKeesport, Erie, Homestead, Finleyville, and Irwin, Pa.

SHIPPED: On unknown dates, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "For Scientific Body Analysis The Ellis Micro-Dynamometer Mfd. by Ellis Research Laboratories, Inc. Chicago U.S.A."

RESULTS OF INVESTIGATION: Examination indicated that the devices were essentially galvanometers for measuring electrical currents and electrical potentials of small magnitude. Each device was mounted in a metal cabinet, on the face of which was a scale or meter intended to measure the flow of current in milliamperes, together with a number of dials which could be set at numbered or lettered positions. The dial settings were intended to increase or decrease the resistance to the current flowing through the device. The current which flowed and was measured by the scale or meter was generated by closing the circuit between two dissimilar metal "probes." The circuit was closed by placing the "probes" at different points on the human body, by placing the "probes" together, or by immersing them in water.

LIBELED: 10-9-62, W. Dist. Pa.

CHARGE: 502(a)—when shipped, the labeling of the article contained statements which represented and suggested that the article of device was adequate and effective for diagnosing disease, which statements were false and misleading since the device was not adequate and effective for diagnosing disease; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use and it was not entitled to any exemption from that requirement.

DISPOSITION: On 10-29-62, George P. Buell, D.C., claimed the device which had been located at Finleyville, Pa., denied that the device claimed was misbranded and averred that there was nothing on the labeling, as stated in the libel, which represented or suggested that the article of device was adequate and effective for diagnosing disease. And further, that the statements on the label were not false and misleading in that the label merely indicated that the device was a galvanometer used for "Scientific Body Analysis," i.e., to measure such changes in voltage as may exist on the surface of the human body by the use of such galvanometer as may occur under certain circumstances, and not for the purpose of diagnosing disease. The claimant further denied that the device was held illegally or that it was liable to seizure and condemnation, the claimant alleging that his device contained a label stating "Galvanometer, Used for Research" and that any and all labels on the device, which may or was alleged to be illegal, had been removed and made to conform to the law and therefore was not held illegally. On 12-28-62, the Government served written interrogatories on the claimant.

On 1-4-63, a default decree of condemnation and destruction was filed with respect to the devices at McKeesport, Erie, Homestead, and Irwin, but not with respect to the device at Finleyville, claimed by George P. Buell.

On 1-18-63, the claimant filed answers to the Government's interrogatories. On 3-28-63, a hearing was held in open court, after which the court agreed to the Government's request for summary judgment. On 4-4-63, the court granted summary judgment for the Government and ordered the destruction of the remaining device.

7703. Micro-Dynameter devices (5 seizure actions). (F.D.C. Nos. 48308, 48334, 48469, 48472, 48699. S. Nos. 71-278 T; 33-602 V; 16-324 V; 36-322 V; 10-168 V.)

QUANTITY: 6 devices, at Hobart, Okla., Reedsburg, Wis., Louisville, Ky., Birmingham, Ala., and Brockway, Pa.

SHIPPED: Between 1-1-54 and 9-8-61, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "For Scientific Body Analysis The Ellis Micro-Dynamometer Mfd. by Ellis Research Laboratories, Inc., Chicago U.S.A."

LIBELED: 10-26-62, 10-26-62, 12-6-62, 12-28-62, 2-8-63; W. Dist. Okla., W. Dist. Wis., W. Dist. Ky., N. Dist. Ala., W. Dist. Pa.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the devices were adequate and effective for diagnosing disease; and 502(f) (1)—the labeling of the articles failed to bear adequate directions for use and they were not entitled to any exemption from that requirement.

DISPOSITION: 12-12-62; 11-29-62; 2-12-63; 1-28-63; 4-10-63. Default—4 devices destroyed and 2 devices delivered to the Food and Drug Administration.

7704. Micro-Dynamometer devices (21 seizure actions). (F.D.C. Nos. 47912, 47931, 47932, 47937, 47959, 47963, 48016, 48077, 48218, 48313, 48320, 48323, 48465, 48500, 48507. S. Nos. 73-011/12 T; 54-699/700 T, 54-961 T; 7-988 T, 8-674 T, 8-767 T, 62-101 T; 19-235 T, 56-948 T, 71-402 T, 71-482/3 T; 51-176/7 T, 51-259 T; 40-397/8 T, 40-544/5 T, 73-897 T, 74-161/3 T; 59-589/90 T; 74-329 T, 74-354 T, 74-454 T; 88-941 T; 67-670 T, 89-064 T; 42-082 V, 42-201 V; 9-201/2 V; 36-964/5 V, 36-967 V; 16-887/8 V, 17-074 V; 36-536/7 V.)

QUANTITY: 46 devices at Buffalo and Kenmore, N.Y.; Waynesville, Franklin, and Asheville, N.C.; Waterbury, Hartford, East Hartford, and New Milford, Conn.; Port Lavaca, Sinton, Freeport, Conroe, and Alvin, Tex.; Portland and Cottage Grove, Oreg.; Rockville Centre, East Meadow, Long Island City, Forest Hills, Jackson Heights, Brooklyn, and Jamaica, N.Y.; Baton Rouge, La.; Long Island City, Hollis, and Brooklyn, N.Y.; Grand Rapids, Mich.; Peru and Plymouth, Ind.; East Stroudsburg and Pittston, Pa.; Watervliet and Schuylerville, N.Y.; Fayette, Hamilton, and Sheffield, Ala.; Louisville, Ky.; and Athens, Ala.

SHIPPED: On various dates, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABELS IN PART: (Control panel) "Manufactured by Ellis Research Laboratories, Inc., Chicago * * * The Ellis Micro-Dynamometer" and (metal plate) "For Scientific Body Analysis The Ellis Micro-Dynamometer Mfd. by Ellis Research Laboratories, Inc., Chicago, U.S.A."

ACCOMPANYING LABELING: Literature pertaining to the device.

LIBELED: 8-1-62, W. Dist. N.Y.; 8-13-62, W. Dist. N.C.; 8-11-62, Dist. Conn.; 8-16-62 and 8-17-62, S. Dist. Tex.; 8-15-62, Dist. Oreg.; 8-13-62, E. Dist. N.Y.; 9-10-62, E. Dist. La.; 9-4-62, E. Dist. N.Y.; 10-8-62, W. Dist. Mich.; 10-16-62, N. Dist. Ind.; 10-16-62, M. Dist. Pa.; 10-22-62, N. Dist. N.Y.; 12-28-62, N. Dist. Ala.; 1-3-63, W. Dist. Ky.; and 1-9-63, N. Dist. Ala.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for diagnosing disease; and 502(f) (1)—the labeling of the articles failed to bear adequate directions for use and they were not entitled to any exemption from that requirement.

DISPOSITION: 10-31-62; 11-13-62; 9-15-62; 10-29-62, 10-24-62, 10-25-62, 10-30-62, 10-25-62; 10-12-62; 10-17-62; 2-18-63; 10-17-62; 12-7-62; 6-7-63; 11-16-62; 3-27-63; 1-28-63; 3-19-63; and 2-11-63. Default—12 devices delivered to the Food and Drug Administration and 34 devices destroyed.

7705. Micro-Dynamometer devices (4 seizure actions). (F.D.C. Nos. 47903, 47907, 47917/18. S. Nos. 77-273 T; 62-056 T; 43-008/9 T; 43-010 T, 44-611 T.)

QUANTITY: 6 devices, at Asheville, N.C.; Chicago, Ill.; York, Schuylkill Haven, and Morrisville, Pa.

SHIPPED: Between 4-30-47 and 6-12-62, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "The Ellis Micro-Dynamometer Mfd. by Ellis Research Laboratories, Inc., Chicago."

ACCOMPANYING LABELING: One or more of the following pieces of literature entitled: "Micro-Dynamometer News, Vol.-No. 1 July 1946"; "Journal of Micro-Dynamometer Research No. J-6 [or "J-7," "J-8," "J-11," "J-12," "J-14a," "J-16," "J-17"]"; "Bulletin of Micro-Dynamometer Research Association No. 1a [or "2a," "4a," "7," "9," "10"]"; "Bulletin of Micro-Dynamometer, No. J-1"; "Bulletin of Ellis Research Laboratories, Inc., M-2, Jan. 1951 [or "M-3 Sept., 1946"]"; "Bulletin T-3 [or "T-3a," "T-4"]"; "Volume 1 No. 1 Micro-Dynamometer Vivo-Tone Guide * * * Ellis Research Laboratories, Inc."; "Effective Feb. 3, 1957 Micro-Dynamometer Parts, Accessories, Supplies and Services"; "Supplement to Micro-Dynamometer Handbook"; "The Ellis Advanced Instrument for Precision Clinical Measurement"; "Simplified Chiropractic," by Lyle Albert, D.C.; and chart entitled "Micro-Dynamometer Index Chart."

LIBELED: 7-25-62, 7-26-62, 7-30-62, 7-31-62; W. Dist. N.C., N. Dist. Ill., M. Dist. Pa., E. Dist. Pa.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for diagnosing disease; and 502(f) (1)—the labeling of the articles failed to bear adequate directions for use and they were not entitled to any exemption from that requirement.

DISPOSITION: 11-13-62, 9-11-62, 8-21-62, 9-26-62. Default—1 device delivered to the Food and Drug Administration and 5 devices destroyed.

DRUGS FOR VETERINARY USE*

7706. Medicated feed. (F.D.C. No. 46388. S. Nos. 8-072 R, 8-074/5 R.)

INFORMATION FILED: 5-7-62, N. Dist. N.Y., against Ogden Grain Co., Inc., a corporation, Utica, N.Y.

SHIPPED: 6-20-60 and 11-28-60, from Utica, N.Y., to Thomaston, Conn.

LABEL IN PART: (Tags affixed to bags) "100 Lbs. Net Ogden Complete Chick Starter Guaranteed Analysis Protein-20.0% Fat-4.0% Fibre-6.0% Ingredients Wheat Standard Middlings, Ground Barley, Ground Oats, Animal Fat, * * * Salt, Bone Charcoal, Animal Fat Stabilized with Butylated-Hydroxy-Toluene, Menadione Sodium Bisulfite. .0175 SQ Manufactured by Ogden Grain Co. Utica, N.Y.," "OGDEN Hi-Energy Laying Mash Medicated * * * Active Drug Ingredient Arsanilic Acid. . . 0.01% Guaranteed Analysis Crude Protein-16.0% Crude Fat-4.5% Crude Fibre-4.0% Ingredients * * * Manufactured by Ogden Grain Co. Utica, N.Y.," and "100 Lbs. Net Ogden Big 'O' Hi-Energy Laying Mash Medicated * * * Active Drug Ingredient: Oxytetracycline Hydrochloride (Terramycin) 50 gms. per ton Guaranteed Analysis Crude Protein-16.0% Crude Fat-4.5% Crude Fibre-4.0% Ingredients Corn Meal, Wheat Standard Middlings, * * * Crumbles Manufactured by Ogden Grain Co. Utica, N.Y."

*See also No. 7687.

CHARGE: *Chick Starter*, 502(e) (2)—when shipped, the article failed to bear the common or usual name of the active ingredient, sulfaquinoxaline, contained therein; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use.

OGDEN Hi-Energy Laying Mash Medicated, 501(c)—when shipped, the strength of the article differed from that which it purported and was represented to possess in that it was represented to contain .01 percent arsanilic acid, and it contained less.

Ogden Big "O" Hi-Energy Laying Mash Medicated, 502(e) (2)—when shipped, the label of the article failed to bear the name and quantity or proportion of the derivative or preparation of arsenic, namely, arsanilic acid, contained in the article.

PLEA: Guilty.

DISPOSITION: 12-17-62. \$600 fine.

7707. Milk-A-Way Minerals with Sulphas. (F.D.C. No. 48129. S. No. 33-434 T.)

QUANTITY: 17 2½-lb. jars and 5 10-lb. jars at Arlington, Iowa.

SHIPPED: 8-8-62, from Kenyon, Minn., by Kenyon Vet Supply.

LABEL IN PART: (Jar) "Milk-A-Way Combination of Minerals with Sulphas For Aid in the Treatment of Mastitis Manufactured by Kenyon Vet Supply * * * Kenyon, Minnesota * * * Ingredients * * * Drug Ingredients Sulphanilamide, not less than 60 gr. per lb. Sulphathiazole, not less than 60 gr. per lb. Sulphaniethazine, not less than 60 gr. per lb. Sodium bicarbonate, not less than 300 gr. per lb. Drugs used in this degree leave no drug residue in the milk Feeding Directions."

RESULTS OF INVESTIGATION: Analysis showed that the article contained essentially the amount of sulfonamides declared on the label.

LIBELED: 9-28-62, N. Dist. Iowa.

CHARGE: 502(a)—when shipped, the label contained false and misleading representations that the article was adequate and effective as a treatment for overcoming mastitis; 502(a)—the label statement "Drugs used in this degree leave no drug residue in the milk" was misleading since the label failed to state the material fact that when this article was used as directed, the dosage levels were insufficient to provide therapeutically effective amounts of the sulfonamides for the intended purpose, and the material fact that if therapeutically effective amounts of sulfonamides were present and this article were used at effective dosage levels, the milk of treated animals would contain drug residues; and 502(f) (2)—the labeling failed to bear the warning statement that a veterinarian should be consulted if symptoms persisted for more than 2 or 3 days.

DISPOSITION: 11-16-62. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICES FOR HUMAN USE*

7708. Various drugs. (F.D.C. No. 46727. S. Nos. 8-539 R, 14-427/8 R, 20-022 R, 47-922 R, 79-384 R, 4-390 T, 15-464 T.)

INFORMATION FILED: 9-13-62, S. Dist. Ohio, against C. M. Bundy Co., a corpora-

*See also Nos. 7686, 7689.

tion, Cincinnati, Ohio, Walter F. Wargell, president, and Robert S. Justice, vice president.

ALLEGED VIOLATIONS: Between 9-20-58 and 9-29-60, the defendants shipped in interstate commerce, from Cincinnati, Ohio, various quantities of adulterated and misbranded *ergonovine maleate tablets*, adulterated *calcium carbonate tablets*, adulterated *ammonium chloride tablets*, adulterated and misbranded *nitroglycerin digitalis compound tablets*, and adulterated and misbranded *Special Formula No. 3-12890 tablets*, to Lafayette and Muncie, Ind., Jackson, Mich., and Rochester, N.Y.

On 11-28-59, the defendants caused to be given to a firm engaged in the business of shipping drugs into interstate commerce, a guaranty to the effect that the products shipped by the defendants to such firm under the guaranty would not be adulterated or misbranded, and, on 6-2-60, the defendants caused to be shipped to the holder of the guaranty, at Mansfield, Ohio, a number of adulterated and misbranded *Special Formula No. 3-13597 tablets*.

LABEL IN PART: (Drum) "The C. M. Bundy Co. * * * Cincinnati 2, Ohio Special Formula No. 1-B.A.X. Manufactured for Lafayette Pharmacal, Inc. * * * Each tablet represents: Ergonovine Maleate 0.2 mg."; (pkg.) "Tablet Nitroglycerin Digitalis Comp. (Dacosta) Each tablet represents: Nitroglycerin 1/100 gr. Tinct. Digitalis 3 Min. Tinct. Strophanthus 1 Min. (Quabain 0.0055 gr.) Tinct. Belladonna 3/8 gr. (Total Alkaloids 0.00011 gr.) Distributed by Noble-Blackmer, Inc. Jackson, Michigan," and (ctn.) "The C. M. Bundy Co. * * * Cincinnati 2, Ohio Special Formula No. 3-12890 Manufactured for The Paine Drug Company * * * Each tablet represents: Tr. Belladonna 1/4 MIN (Total alkaloids 0.000075 gr.) Tr. Strophanthus 1 MIN (Quabain 0.0055 gr.) Tr. Digitalis 3 MIN Nitroglycerin 1/100 gr."

CHARGE: *Ergonovine maleate tablets*, 501(b)—when shipped, the article purported to be ergonovine maleate, and its strength differed from and its quality and purity fell below, the standard set forth in the United States Pharmacopeia since the article consisted of ergotamine tartrate; 501(d) (2)—ergotamine tartrate had been substituted for ergonovine maleate; and 502(a)—the designation "Ergonovine Maleate" displayed upon the article was false and misleading since the article was ergotamine tartrate.

Calcium carbonate tablets, 501(b)—when shipped, the quality of the article fell below the standard set forth in the National Formulary X since it failed to meet the compendium's disintegration requirement.

Ammonium chloride tablets, 501(b)—when shipped, the quality of the article fell below the standard set forth in the National Formulary X since it failed to meet the compendium's disintegration requirement for enteric-coated tablets.

Nitroglycerin digitalis compound tablets, *Special Formula No. 3-12890 tablets*, and *Special Formula No. 3-13597 tablets*, 501(c)—when shipped, the strength of the articles differed from that which they were represented to possess, since each tablet contained no nitroglycerin; and 502(a)—the statement "Each tablet represents: Nitroglycerin 1/100 gr." displayed on the package, carton, or box was false and misleading since each tablet contained no nitroglycerin.

PLEA: Guilty by the corporation to all counts; and by the individuals to the two counts involving the "*ergonovine maleate*" tablets.

DISPOSITION: 1-11-63. Corporation—\$2,000 fine, of which \$1,800 was suspended; each individual—\$200 fine, of which \$150 was suspended.

7709. Imitation Dexedrine Sulfate tablets and imitation Serpasil tablets.
(F.D.C. No. 47312. S. Nos. 45-627 R, 45-631 R.)

INFORMATION FILED: 7-20-62, M. Dist. N.C., against Lyle B. Craig, t/a Craig Drug Co., Aberdeen, N.C.

ALLEGED VIOLATIONS: Between 6-1-60 and 12-6-60, the defendant caused a quantity of dextro-amphetamine sulfate tablets to be repacked in a bottle labeled "Dexedrine Sulfate" and a quantity of reserpine tablets to be repacked in a bottle labeled "Serpasil," which acts resulted in the tablets being adulterated and misbranded.

CHARGE: 501(d) (2)—*imitation Dexedrine Sulfate tablets* were substituted for Dexedrine Sulfate tablets, and *imitation Serpasil tablets* were substituted for Serpasil tablets; 502(a)—the label statements "tablets 5 mg. DEXEDRINE Sulfate * * * S.K.F." and "tablets 0.25 mg. each SERPASIL * * * CIBA" were false and misleading; 502(i) (2)—the articles were imitations of other drugs, namely, Dexedrine Sulfate and Serpasil; and 502(i) (3)—the articles were offered for sale under the names of other drugs, namely, Dexedrine Sulfate and Serpasil.

PLEA: Nolo contendere.

DISPOSITION: 3-11-63. One year in prison suspended and \$500 fine.

7710. Penicillin drugs. (F.D.C. No. 48393. S. Nos. 27-181/5 V.)

QUANTITY: 803 vials (Control No. 07644), 1,697 vials (Control No. 07596), 1,820 vials (Control No. 07632), 3,725 vials (Control No. 07622), and 766 vials (Control No. 07645), at Beverly Hills, Calif.

SHIPPED: Between 9-25-59 and 9-18-62, from Los Angeles, Calif., by Maurry Biological Co., Inc., to Des Moines, Iowa, and returned to Beverly Hills, Calif., on 9-25-62.

LABEL IN PART: (Vial) "Pen-AQ 100 cc Multiple Dose Sterile Vial 300,000 U. per cc. with 2% Procaine Hydrochloride * * * Control No. 07644 [or "07622"]" and "Pen-di-Strep 10 cc Multiple Dose Sterile Vial Each 2 cc contains 400,000 Units Procaine Penicillin G, U.S.P. suspended * * * Control No. 07596 [or "07632" or "07645"]."

RESULTS OF INVESTIGATION: Analyses showed that the articles listed below contained the following percentages of penicillin potency: *Pen-AQ*, Control No. 07644, 84.7%; *Pen-di-Strep*, Control No. 07596, less than 17.7%; *Pen-di-Strep*, Control No. 07632, 69%; and *Pen-di-Strep*, Control No. 07645, 73%. The article *Pen-AQ*, Control No. 07622, contained approximately the declared potency of penicillin.

LIBELED: 12-4-62, S. Dist. Calif.

CHARGE: 501(b)—when shipped, the strength of the article (*Pen-AQ*, Control No. 07644) differed from the standard for procaine penicillin G suspension set forth in the United States Pharmacopeia; 501(c)—the strength of the articles (*Pen-di-Strep*) differed from that which they purported to possess; 502(a)—the labels of the articles (*Pen-AQ*, Control No. 07644 and all lots of *Pen-di-Strep*) bore false and misleading representations with respect to their penicillin potency; and 502(e) (2)—the labels of the articles (*Pen-AQ*, Control Nos. 07644 and 07622) failed to declare the common or usual name of each active ingredient, since the ingredient, penicillin, was not declared.

DISPOSITION: 3-8-63. Default—destruction.

7711. Insta-Pep tablets. (F.D.C. No. 46764. S. Nos. 13-787/8 T.)

QUANTITY: 297 combination pkgs., each containing 1 50-tablet btl. and 1 25-tablet btl., and 301 individually ctnd. 25-tablet btls., at Chicago, Ill.

SHIPPED: Between the approximate dates of 11-30-59 and 3-8-61, from New York, N.Y.

LABEL IN PART: (Btl. and ctn.) "Insta-Pep with Dynamol and 'Vitamin Feed' For prolonged Vitamin-Mineral Release A high potency therapeutic Vitamin-Iron Formula Sole Distributors: Drug Research Corp., New York, N.Y. Each Tablet Contains: * * * Cobalamin Concentrate (Vit. B₁₂ Activity) 3.0 mcg. Dynamol (D.R.C. Brand of Caffeine Alkaloid Anhydrous) 3.0 gr. * * * A stimulant and therapeutic Formula" and (combination pkg.) "Insta-Pep A Fast-Acting Stimulant Combined With High Potency Vitamin-Iron Formula Each Tablet Releases Vitamins-Minerals Three Times a Day."

RESULTS OF INVESTIGATION: Analysis showed the article to contain about 50 percent of the declared amount of vitamin B₁₂.

LIBELED: 12-1-61, N. Dist. Ill.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; 502(a)—the label statement "Cobalamin Concentrate (Vit. B₁₂ Activity) 3.0 mcg." was false and misleading; and 502(a)—when shipped, the name "*Insta-Pep*" and certain statements on the label represented and suggested that the article was adequate and effective to provide instant pep, which name and statement were false and misleading since the article was not adequate and effective for such purpose; and the label also represented and suggested that the article was a high-potency therapeutic vitamin and iron formula and that "Dynamol" was an important active ingredient, which statements were false and misleading since they were contrary to fact.

DISPOSITION: Drug Research Corp., New York, N.Y., claimant, filed an answer denying that the article was misbranded. The Government filed a motion for summary judgment and this was denied on 6-4-62. On 1-4-63, the claimant having conceded that the vitamin B₁₂ component of the article had deteriorated, and therefore consented to a decree adjudging the article adulterated as alleged, judgment of condemnation was entered without prejudice to the Government to subsequently initiate action on basis of allegations of misbranding and without prejudice to claimant to defend against such allegations. The article was ordered destroyed.

7712. Vi-Ron-Ite tonic. (F.D.C. No. 48400. S. No. 16-153 V.)

QUANTITY: 49 cases, each containing 12 individually ctnd. btls., at Barbourville, Ky.

SHIPPED: 4-27-62, from Cincinnati, Ohio, by C. M. Bundy Co.

LABEL IN PART: (Btl.) "Vi-Ron-Ite A High Potency Tonic of Therapeutic Strength * * * Each Fluid Ounce (2 Tablespoonfuls) Represents: B₁ (Thiamin) 10 mg. * * * Effective as an aid to normal energy metabolism * * * Contents 12 fluid Ounces Distributed by Dwight L. Brown Enterprises, Barbourville, Ky."

ACCOMPANYING LABELING: Leaflet in carton "Vi-Ron-Ite The Faster Acting Vitamin Tonic."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 75 percent of the declared amount of vitamin B₁.

LIBELED: 12-11-62, E. Dist. Ky.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; 502(a)—the label statement "Each Fluid Ounce (2 Tablespoonfuls) Represents: B₁ (Thiamin) 10 mg." was false and misleading; and 502(a)—when shipped, the labeling contained false and misleading representations that the article was adequate and effective for the treatment and prevention of anemia, rundown condition, and tiredness; and to promote tissue growth; release body energy; slow down the aging process; retain blood vessel pliability; build muscle and nerve tissue; and promote normal energy metabolism; that the article was a vitamin tonic; and that the article was of unusual significance for special dietary supplementation and therapeutic use because it supplied, in one bottle, as much essential iron as 40 pints of raw oysters, 9 pounds of beefsteak, 93 pounds of spinach, or 160 pounds of fish.

DISPOSITION: 3-7-63. Default—destruction.

7713. Sodium para-aminosalicylic acid tablets (2 seizure actions). (F.D.C. Nos. 43546, 43547. S. Nos. 61-109/11 P, 63-274 P.)

QUANTITY: 879 1,000-tablet btl., 5 cases, each containing 125 250-tablet bags, 59 ctns., each containing 24 1,000-tablet btl., and 9 1,000-tablet btl., at Northville and Detroit, Mich.

SHIPPED: Between 5-22-59 and 6-18-59, from Auburn, Mass., by Cowley Pharmaceuticals, Inc.

LABEL IN PART: (Btl.) "SALAMIN SODIUM Each tablet contains: Sodium Para-Aminosalicylic Acid 0.5 grams—(7.72 grains) * * * Cowley Pharmaceuticals, Inc., Auburn, Massachusetts."

RESULTS OF INVESTIGATION: The 250-tablet bags were repacked from the 1,000-tablet bottles which had been shipped and which were labeled as specified above.

Analysis showed that the various codes of the article contained not more than 90.3 percent, 89.8 percent, 90.6 percent, and 87.2 percent of the labeled amount of sodium para-aminosalicylic acid. The United States Pharmacopeia requires that *sodium para-aminosalicylic acid tablets* contain from 95 to 105 percent of the labeled amount of the drug.

LIBELED: 9-24-59, E. Dist. Mich.

CHARGE: 501(b)—when shipped, the article purported to be a drug recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its quality fell below, the standard set forth in the compendium; and 502(a)—the label statement "Each tablet contains: Sodium Para-Aminosalicylic Acid 0.5 grams (7.72 grains)" was false and misleading.

DISPOSITION: 12-28-60. Consent—claimed by Cowley Pharmaceuticals, Inc., and reconditioned.

7714. Rubber prophylactics. (F.D.C. No. 49075. S. No. 67-538 V.)

QUANTITY: 32,112 prophylactics, each individually foil-wrapped and ctnd., at Durham, N.C., in possession of Barnetts, Inc.

SHIPPED: 3-15-63, from Akron, Ohio, by Allied Latex Sales Co., Inc.

LABEL IN PART: (Unit) "Barnett Packaging Inc. Durham, N.C. Sold For Prevention of Disease Only * * * C-3-63"; (foil-wrap) "Product of Barnetts, Inc., Durham, N.C. Sold For The Prevention of Disease Only Aztec Pro-

phylactic * * *"; (ctn.) "Aztec 'ready-wet' Prophylactics * * * Package of One * * * Sold and Intended To Be Used As A Preventive of Disease Only * * * Product of Barnett Dist. Co. Durham, N.C."

RESULTS OF INVESTIGATION: The prophylactics were shipped individually foil-wrapped in bulk lots and thereafter were repacked by Barnetts, Inc., into individual cartons. Examination indicated that 2.08 percent of the prophylactics contained holes.

LIBELED: 6-17-63, M. Dist. N.C.

CHARGE: 501(c)—when shipped and while held for sale, the quality of the article fell below that which it purported to possess; 502(a)—the label statements "Sold For The Prevention of Disease Only" and "Sold and Intended To Be Used As A Preventive of Disease Only" were false and misleading as applied to a product containing holes; and 502(b) (1)—the labeling stated that the article was a product of Barnett Distributing Co., which was contrary to fact since the firm was a repacker and distributor only.

DISPOSITION: 7-25-63. Default—destruction.

7715. Rubber prophylactics. (F.D.C. No. 48276. S. No. 20-404 V.)

QUANTITY: 12 ctns., each containing 12 boxes of 12 individually foil-wrapped prophylactics, at Dallas, Tex.

SHIPPED: 10-1-62, from North Kansas City, Mo., by Dean Rubber Manufacturing Co.

LABEL IN PART: (Box) "Peacocks Redi-Wet Rubbers In Foil Hygienically Lubricated Dean Rubber Mfg. Co. North Kansas City, Mo. No. 12 * * * An Aid in preventing venereal diseases."

RESULTS OF INVESTIGATION: Examination of 288 prophylactics showed that 1.04 percent were defective in that they contained holes.

LIBELED: On or about 12-10-62, N. Dist. Tex.

CHARGE: 501(c)—when shipped, the quality of the article differed from that which it was purported to possess; and 502(a)—the label statement "An Aid in preventing venereal diseases" was false and misleading as applied to a product containing holes.

DISPOSITION: 1-31-63. Default—destruction.

7716. Rubber prophylactics. (F.D.C. No. 49009. S. No. 57-727 V.)

QUANTITY: 23 ctns., each containing 48 3-unit pkgs., at White Bear Lake, Minn.

SHIPPED: 5-2-63 and 5-20-63, from North Kansas City, Mo., by Dean Rubber Manufacturing Co.

LABEL IN PART: (Unit) "Peacock's Dean Rubber Mfg. Co. No. K.C. Mo."

RESULTS OF INVESTIGATION: Examination showed that approximately 2 percent of the articles contained holes.

LIBELED: 6-17-63, Dist. Minn.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "An Aid In Preventing Venereal Disease" was false and misleading as applied to a product containing holes.

DISPOSITION: 7-30-63. Default—destruction.

7717. Rubber prophylactics. (F.D.C. No. 49011. S. No. 57-726 V.)

QUANTITY: 22 ctns., each containing 12 12-unit boxes, at St. Paul, Minn.

SHIPPED: 5-6-63, from North Kansas City, Mo., by Dean Rubber Manufacturing Co.

LABEL IN PART: (Box) "One Dozen Peacocks Redi-Wets In Foil—Dean Rubber Mfg. Co. North Kansas City, Mo."

RESULTS OF INVESTIGATION: Examination showed that approximately 1.78 percent of the article contained holes.

LIBELED: 6-20-63, Dist. Minn.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "An Aid In Preventing Venereal Diseases" was false and misleading as applied to a product containing holes.

DISPOSITION: 8-2-63. Default—destruction.

DRUGS FOR VETERINARY USE*

7718. Medicated feed. (F.D.C. No. 48172. S. Nos. 6-564/6 T, 6-638 T, 7-476 T, 7-541 T.)

INFORMATION FILED: 6-7-63, Dist. Mass., against Wirthmore Feeds, Inc., Waltham, Mass.; Eastern Grain Co., Bridgewater, Mass.; St. Albans Grain Co., St. Albans, Vt.; and Crosby Milling Co. (Div. of Cutler Co.), Brattleboro, Vt., corporations.

SHIPPED: Between 10-18-61 and 1-19-62, from Bridgewater, Mass., to Danielson, Conn.; from St. Albans, Vt., to Ware, Mass., and through Massachusetts to Milford, Conn.; and from Brattleboro, Vt., through Massachusetts to North Bangor, Maine.

LABELS IN PART: (100-lb. bag tags) "WIRTHMORE MEDICATED TREAT 431 Active Drug Ingredient FURAZOLIDONE .022% WIRTHMORE FEEDS INC. Waltham, Mass.," "WIRTHMORE POULTRY WORMER ACTIVE DRUG INGREDIENTS Piperazine, .125% (equivalent to Piperazine Phosphate, 3%) Phenothiazine, .45% Manufactured for WIRTHMORE FEEDS INC., Waltham, Mass.," "WIRTHMORE MEDICATED QUICKIES ACTIVE DRUG INGREDIENT CHLORTETRACYCLINE HYDROCHLORIDE 0.1 grams per Pound (200 grams per Ton) WIRTHMORE FEEDS INC., Waltham, Mass.," "WIRTHMORE MEDICATED PIG ZIP FOR SWINE ONLY ACTIVE DRUG INGREDIENTS ARSANILIC ACID, .008% HYGROMYCIN B, .006 gm., (6,000 units) per pound WIRTHMORE FEEDS INC. Waltham, Mass.," "CAKLEBIRD CHICK STARTER 952 ACTIVE DRUG INGREDIENT Sulfaquinolaxaline .0175% Manufactured for PENOBSCOT POULTRY CO., INC. BELFAST, MAINE," and "WIRTHMORE POULTRY WORMER ACTIVE DRUG INGREDIENTS PIPERAZINE, .125% (Equivalent to Piperazine Dihydrochloride, .23%) PHENOTHIAZINE, .45% WIRTHMORE FEEDS INC., Waltham, Mass."

RESULTS OF INVESTIGATION: Analysis revealed that the articles were from 86 to 24 percent deficient in various drug ingredients; and investigation indicated that the *Medicated Pig Zip* bore the wrong label.

CHARGE: *Medicated Treat*, 501(c)—when shipped, the strength of the article

*See also Nos. 7687, 7688, 7706.

differed from that which it was represented to possess; and 502(a)—the statement "FURAZOLIDONE .022%" was false and misleading.

Poultry Wormer, 501(c)—when shipped, the strength of the article differed from that which it was represented to possess; and 502(a)—the statements "Piperazine, .125%" and "Phenothiazine, .45%" were false and misleading.

Medicated Quickies, 501(c)—when shipped, the strength of the article differed from that which it was represented to possess; and 502(a)—the statement "CHLORTETRACYCLINE HYDROCHLORIDE 0.1 grams per Pound" was false and misleading.

Medicated Pig Zip, 501(c)—when shipped, the strength of the article differed from that which it was represented to possess; 501(d) (2)—a medicated feed containing furazolidone in the approximate amount of .0046%, arsanilic acid in an amount less than 0.008%, and hygromycin B in an amount less than 0.006 gram per pound, had been substituted for the medicated feed containing drug ingredients consisting of arsanilic acid in the amount of 0.008%, and hygromycin B in the amount of 0.006 gram per pound, which said drug purported and was represented to be; 502(a)—the statements "ARSANILIC ACID, .008%" and "HYGROMYCIN B, .006 gm., (6,000 units) per pound" were false and misleading; 502(a)—the statement "For control of infestations of Large Roundworms (*Ascaris*), Nodular Worms (*Oesophagostomum*), and Whipworms (*Trichuris*)" was false and misleading in that the drug was not adequate and effective for the control of such infestations; and 502(e) (2)—the label of the article failed to bear the common or usual name of each active ingredient, since it failed to bear the name of the active ingredient, furazolidone.

Chick Starter, 501(c)—when shipped, the strength of the article differed from that which it was represented to possess; and 502(a)—the statement "Sulfa-quinoxaline .0175%" was false and misleading.

PLEA: Nolo contendere by Wirthmore Feeds, Inc., to all 12 counts; and guilty by Eastern Grain Co. to 6 counts, by St. Albans Grain Co. to 4 counts, and by Crosby Milling Co. (Div. of Cutler Co.), to 2 counts.

DISPOSITION: 5-27-63. Wirthmore Feeds, Inc.—\$2,400 fine; Eastern Grain Co.—\$600 fine; St. Albans Grain Co.—\$400 fine; and Crosby Milling Co. (Div. of Cutler Co.)—\$200 fine.

7719. Medicated feed. (F.D.C. No. 48631. S. Nos. 10-006/7 V.)

QUANTITY: 18 50-lb. bags of *Medicated Broiler Mash Crumbles* and 43 50-lb. bags of *Medicated Broiler Mash Pellets*, at Butler, Pa., in possession of P. J. Oesterling & Son, Inc.

SHIPPED: The active drug ingredient was shipped on 2-13-62, from Teterboro, N.J.

LABEL IN PART: (Bag) "Sun Side Rapid Gro Broiler Mash Medicated * * * CRUMBLES [or "Rapid Gro Broiler Mash Medicated * * * PELLETED"] To aid in preventing outbreaks of coccidiosis. Also for promotion of growth and improved feed efficiency. Active Drug Ingredients: Amprolium * * * (Amprol) 0.0125% * * * Ingredients: Corn Meal, Alfalfa Meal, Soy Bean Oil Meal, Meat Scraps, Wheat Middlings, * * * and Antibiotic Feed Supplement * * * Manufactured by P. J. Oesterling & Son, Inc. Mills at Butler, Pa."

RESULTS OF INVESTIGATION: The Pellets contained approximately 45 percent of the declared amount of amprolium, and the Crumbles, 4 percent. The articles

were manufactured by the dealer from various ingredients including the active drug ingredient, amprolium.

LIBELED: 2-8-63, W. Dist. Pa.; libel amended 3-8-63.

CHARGE: 501(c)—while held for sale, the strength of the articles differed from that which they purported to possess; and 502(a)—the label statement “Amprolium * * * (Amprol) 0.0125%” was false and misleading as applied to a product containing less than the declared amount of amprolium.

The articles were also alleged to be misbranded under the provisions of the Act applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 4-11-63. Consent—claimed by P. J. Oesterling & Son, Inc., and released under bond to be brought into compliance with the law.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS AND DEVICES FOR HUMAN USE*

7720. Millrue Iron Tonic, Soy Germ Oil tablets and Phyl-In Alfa tablets. (F.D.C. No. 47361. S. Nos. 16-752 R, 62-941 R, 12-914 T, 12-916 T, 15-344 T, 15-346/7 T.)

INFORMATION FILED: 3-20-63, S. Dist. Ind., against Will H. Roberts, t/a Roberts Health Center, Evansville, Ind.

ALLEGED VIOLATION: Between 6-9-61 and 10-11-61, the defendant caused *Millrue Iron Tonic*, *Soy Germ Oil tablets*, and *Phyl-In Alfa tablets* to be shipped from Boonville, Ind., York, Pa., and Carlock, Ill., to Cincinnati, Ohio, Louisville, Ky., and Racine, Wis. Between 9-18-61 and 12-5-61, the defendant caused quantities of *Millrue Iron Tonic* and *Phyl-In Alfa tablets* to be held for sale at Evansville, Ind., for use in the treatment and prevention of various diseases and conditions for which the articles were not adequate and effective, which acts resulted in the articles being misbranded.

LABEL IN PART: (Btl.) “MILLRUE IRON TONIC HEMATINIC Directions Manufactured by MILLPAX, * * * Carlock, Illinois”; (canister) “SOY GERM OIL TABLETS Formula 671—Distributed by—YORK BARBELL COMPANY York, Pa.”; and (btl.) “NUTRI-BOOSTER BRAND PHYL-IN ALFA Directions: ROBERTS HEALTH CENTER Boonville, Indiana.”

ACCOMPANYING LABELING: Price list reading in part “Roberts Health Center * * * Milrue * * * Phyl-In-Alfa * * * Soy Germ Oil” and various letters signed “Will H. Roberts” and dated 1-10-61, 6-1-61, 6-8-61, 6-16-61, 7-3-61, 10-4-61, and 11-18-61.

CHARGE: *Millrue Iron Tonic* shipped to Cincinnati, 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the treatment and prevention of tumors, colitis, ulcers, piles, and asthma, and that when used in conjunction with the articles of drug described in the accompanying labeling by the names, *Soy Germ Oil tablets* and *Phyl-In-Alfa*, it was adequate and effective for the treatment and prevention of malignant cysts and malignancies.

Soy Germ Oil tablets shipped to Louisville, 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the treatment of muscular dystrophy, and that when used in conjunction with the articles of drug described in

*See also Nos. 7682, 7690, 7691, 7693, 7694, 7697, 7698, 7700-7705, 7708-7717.

the accompanying labeling by the names, *Milrue Iron Tonic* and *Phyl-In-Alfa*, it was adequate and effective for the treatment and prevention of malignancies, tumors, colitis, ulcers, piles, asthma, and arthritis.

Phyl-In Alfa tablets shipped to Louisville, 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the treatment and prevention of tumors, colitis, ulcers, piles, asthma, and arthritis, and that when used in conjunction with the articles of drug described in the accompanying labeling by the names, *Milrue Iron Tonic* and *Soy Germ Oil tablets*, it was adequate and effective for the treatment and prevention of skin cancer, malignant nodules, malignant cysts, inoperable cancer, black cancer, lung cancer, and malignancies.

Milrue Iron Tonic shipped to Racine, 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the treatment and prevention of cancer, tumors, colitis, ulcers, piles, and asthma.

Soy Germ Oil tablets shipped to Racine, 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the treatment and prevention of all wasting diseases, and that when used in conjunction with the articles of drug described in the accompanying labeling by the names, *Milrue Iron Tonic* and *Phyl-In-Alfa*, it was adequate and effective for the treatment and prevention of tumors, colitis, ulcers, piles, asthma, neuritis, and arthritis.

Milrue Iron Tonic at Evansville, 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the treatment and prevention of tumors, colitis, ulcers, piles, and asthma.

Phyl-In Alfa tablets at Evansville, 503(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the treatment and prevention of tumors, colitis, ulcers, piles, asthma, and arthritis.

PLEA: Guilty.

DISPOSITION: 5-27-63. Suspended sentence of 2 years' imprisonment, \$650 fine, plus costs, and 2 years' probation.

7721. Super-Coronaïd tablets. (F.D.C. No. 44373. S. No. 56-701 P.)

QUANTITY: 13 180-tablet btl., 16 60-tablet btl., and 12 360-tablet btl., at Orlando, Fla., in possession of Chamberlin Natural Foods.

SHIPPED: Between 6-11-59 and 12-11-59, from New York, N.Y., by Balanced Foods, Inc.

LABEL IN PART: (Btl.) "Super-Coronaïd * * * U.S. Nutrition Products Co., Yonkers, New York, Dist. * * * Super-Coronaïd (4 tablets) supplies 100 milligrams of unsaturated Fatty Acids* (Linoleic and Linolenic Acids) together with 200 milligrams of Inositol*; 160 milligrams dl-methionine*; 500 milligrams Soy Lecithin*; 4000 U.S.P. units Vitamin A (100% MDR+); 400 U.S.P. Units Vitamin D (100% MDR+); 8 micrograms Vitamin B-12 Activity* (From Cobalamin Conc. N.F.); 800 milligrams Choline Bitartrate*; 2.68 milligrams Vitamin B-6**; 100 milligrams Rutin*; 50 milligrams Vitamin C (166% MDR+)."

ACCOMPANYING LABELING: Leaflets entitled "New Hope for Folks Over 40."

RESULTS OF INVESTIGATION: The leaflets which had been supplied by the shipper were used by the dealer to promote sales of the article.

LIBELED: 4-8-60, S. Dist. Fla.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment in the prevention and management of atherosclerosis, coronary heart attacks, and diseased arteries; that use of the article might add years to your life, bring improvement in your health, decrease the cholesterol in the arteries, help prevent coronary heart attack, save you from a sudden heart attack, and help keep your arteries flexible; and that "Coronaid helps to keep the walls of the blood vessels strong."

DISPOSITION: On or about 6-3-60, Milton Okin, t/a U.S. Nutrition Products Co., Yonkers, N.Y., claimed the article and denied that it was misbranded. On 6-14-60, the case was removed to the District of New Jersey. On 2-28-61, the Government served written interrogatories on the claimant. Thereafter, the claimant declined to answer the interrogatories on the ground that the claimant should not be required to answer interrogatories where such answers might tend to incriminate him. On 3-15-61, the claimant filed written interrogatories on the Government. On 2-9-62, a consent decree of condemnation was filed, which permitted the claimant to relabel the article. However, on 3-22-63, an amended consent decree ordered the article's destruction, which was accomplished on 5-15-63.

7722. Davis Union Remedy laxative and component materials. (F.D.C. No. 45281. S. No. 1-711 R.)

QUANTITY: 20 lbs. *solid extract of herbs*, 2½ gals. *cascara sagrada fluidextract* USP, 100 lbs. *epsom salt* USP, 14 ozs. *aspirin*, 264 unlabeled btls. and 316 12-oz. btls. *Davis Union Remedy laxative*, at Pensacola, Fla., in possession of Johns Distributing Co.

SHIPPED: (*Solid extract of herbs* and *cascara sagrada fluidextract*) 8-30-60, from New York, N.Y.; and (*epsom salt* and *aspirin*) prior to 10-14-60, from Mobile, Ala.

LABEL IN PART: (Btl.) "Davis Union Remedy Laxative—Alcohol 1% 12 Fluid Ounces Active Ingredients: * * * Directions: * * * Warning: * * * Manufactured by Johns Distributing Company, * * * Pensacola, Fla."

ACCOMPANYING LABELING: Cartons for repacked article reading in part "12 fluid ounces Davis Union Remedy."

RESULTS OF INVESTIGATION: The bottled article was manufactured by the dealer from the *solid extract of herbs*, *cascara sagrada fluidextract*, *epsom salt*, and *aspirin* mentioned above. Some of the bottles of the laxative were labeled as above and some of the bottles had not been labeled.

LIBELED: 12-12-60, N. Dist. Fla.

CHARGE: 502(a)—while held for sale, the repack carton label of the article contained false and misleading representations that the article was an adequate and effective treatment for removing wastes from the liver and kidneys.

DISPOSITION: On 1-9-61, Bennie Johns, t/a Johns Distributing Co., claimed the articles and denied that they were misbranded. On 4-17-61, the Government filed written interrogatories. On 4-19-61, the matter came for a pretrial hearing but was held in abeyance until 8-24-61, at which time the claimant agreed to enter into a consent decree of condemnation. On or about 12-14-61,

a consent decree of condemnation was filed which provided for the destruction of the labeled bottles and for release of the other articles for relabeling.

7723. Safflower oil capsules. (F.D.C. No. 46937. S. Nos. 39-234 T, 41-707/8 T.)

QUANTITY: 15 100-capsule btl. at Jamaica, N.Y., in possession of United Whelan Corp.; 522 100-capsule btl. at Brooklyn, N.Y., in possession of United Whelan Corp.; and approximately 4,900 capsules, in boxes of 4 plastic bags each, and an undetermined number of 100-capsule btl., at Brooklyn, N.Y., in possession of Halsey Drug Co.

SHIPPED: 12-29-61 and 1-5-62, from Philadelphia, Pa., by Lustgarten Laboratories, and from Newark, N.J., by Encapsulations, Inc.

LABEL IN PART: (Repack btl.) "Whelco Safflower Oil Capsules with Vitamin B₆ As a dietary supplement. Distributed by Whelco Products, Inc., New York, N.Y. Ingredients: Each capsule contains 912 mg. of Safflower Oil* and 0.5 mg. of Vitamin B₆** (Pyridoxine HCl). Calorie Content per capsule 8.2. * * * Directions: * * * 2 capsules 3 times a day * * * Safflower Oil supplies essential unsaturated fatty acids" and (box) "Each capsule contains Safflower Oil 912 mg. (Linoleic Acid 684 mg.) (Oleic Acid 155 mg.) Pyridoxine Hydrochloride 0.5 mg. * * * Encapsulations Incorporated * * * Newark 5, New Jersey."

ACCOMPANYING LABELING: Books entitled "Calories Don't Count" by Herman Taller, M.D.; counter placard and window streamer entitled "Doctor Taller Recommends That You Use Safflower Oil capsules Whelco Brand * * * Book 'Calories Don't Count' on sale here"; window poster reading in part "Doctor Finds Dieters Must Eat Fat to Lose Fat"; a letter headed "Display information * * * Posters Safflower Oil Capsules"; and a number of repack bottle labels.

RESULTS OF INVESTIGATION: The article which was seized in the possession of United Whelan Corp. had been shipped in bulk lots by Lustgarten Laboratories to Halsey Drug Co. which, in turn, repacked the article into the bottles described above and delivered them to the United Whelan Corp.

The article which was seized in the possession of Halsey Drug Co. had been shipped in bulk by Encapsulations, Inc., and a portion had been repacked into bottles bearing the same bottle label as described above. The repack labels for the article were supplied by United Whelan Corp.

LIBELED: 1-23-62, E. Dist. N.Y.

CHARGE: 502(a)—when shipped and while held for sale, the labels of the articles bore the statement (repack label) "As a dietary supplement" and (bulk and repack labels) other statements which represented and suggested that the articles were to be used solely for special dietary supplementation and were of significant value for such purposes by reason of the presence therein of safflower oil, which statements were false and misleading since the articles were intended for drug purposes and since safflower oil in the articles was of insignificant value for special dietary supplementation; and 502(a)—the accompanying labeling contained false and misleading representations that the articles were adequate and effective for the control of body weight and to reduce and maintain slimness even though consuming many thousands of calories daily without regard to the total caloric intake; to lower and control the cholesterol level of the blood; for the treatment and prevention of arteriosclerosis and heartburn; and to improve the complexion; increase resistance to colds and sinus trouble; promote health; and increase sexual drive.

DISPOSITION: 2-16-62. The Halsey Drug Co. having claimed the capsules seized in its possession and consented to the entry of a decree, a decree of condemnation was entered and such capsules were released under bond for relabeling.

3-15-62. (The remaining lots), default—21 copies of "Calories Don't Count" and 21 bottles of capsules were delivered to the Food and Drug Administration and the remainder destroyed.

7724. Ritran tablets. (F.D.C. No. 47964. S. Nos. 47-050/1 T.)

QUANTITY: 12 1,000-tablet btl. and 55 100-tablet btl. of uncoated tablets; 180 100-tablet unlabeled btl., 8 1,000-tablet unlabeled btl., and 55 100-tablet btl., of coated tablets, at Memphis, Tenn., in possession of Noble Massey Co.

SHIPPED: 12-11-61 and 1-11-62, from Lafayette, Ind.

LABEL IN PART: (Btl.) "C-Pab Ritran Dose * * * Supplied by Noble Massey Co. Memphis 3, Tennessee * * * Brand of Therapeutic Dietary Supplement Each Tablet [or "coated tablet"] contains * * *."

ACCOMPANYING LABELING: Detail cards entitled "Brand of 'Ritran' Tablets Specific Therapeutic Dietary Supplement."

RESULTS OF INVESTIGATION: The tablets were shipped in bulk containers (1 lot) and in unlabeled 100-tablet and 1,000-tablet bottles, and were subsequently repacked and/or relabeled by the dealer.

The detail cards were printed on the order of the dealer and were used for the purpose of promoting sales of the articles.

LIBELED: 8-16-62, W. Dist. Tenn.

CHARGE: 502(a)—while held for sale, the labeling accompanying the articles contained false and misleading representations that the articles were adequate and effective for tension headache, neuralgia, neurasthenic syndromes, as an adjunctive therapy for relief of pain associated with certain peripheral vascular disturbances, chronic osteoarthritis, bursitis, and fascitis.

DISPOSITION: The articles were claimed by Noble Massey Co. The claimant consented to the entry of a decree of condemnation without admitting that the articles were misbranded as charged in the libel. The decree was entered on 10-11-62, and the articles were relabeled.

7725. Super-Kalvita-Plus capsules, Cal-Dex capsules, and rectal suppositories. (F.D.C. No. 48136. S. Nos. 68-834/5 T, 68-838 T.)

QUANTITY: 10 15-capsule btl., 108 30-capsule btl., and 30 100-capsule btl., of *Super-Kalvita-Plus*; 219 50-capsule btl. and 1 1,000-capsule btl. of *Cal-Dex*; and 430 boxes, each containing 12 *rectal suppositories*, at Chicago, Ill., in possession of Illinois Herb Co.

SHIPPED: Between 3-7-62 and 7-18-62, from Detroit, Mich., and Cincinnati, Ohio.

LABEL IN PART: (Btl.) "No. 414 Super-Kalvita-Plus * * * As a dietary supplement * * * Each capsule provides the vitamins and minerals as listed. * * * Prepared for and Packed by Illinois Herb Company, Chicago, Illinois" and "No. 700 Cal-Dex Each Capsule Contains * * * As a Dietary Supplement * * * Prepared for and packed by Ill. Herb Co., Chicago, Ill."; and (box) "No. 42A Rectal Suppositories Each Suppository Contains: * * * Directions * * * Warning * * * Distributed by Illinois Herb Co. Chicago, Ill."

ACCOMPANYING LABELING: Booklets entitled "Healthway Products Almanac 1962 Illinois Herb Company."

LIBELED: 10-1-62, N. Dist. Ill.

CHARGE: 502(a)—while held for sale, the labeling accompanying the articles contained false and misleading representations that the articles were adequate and effective: (*Super-Kalvita-Plus capsules*) to promote physical fitness, mental alertness, resistance to infection and disease, and long life with adult vitality and health; and by reason of its vitamin E content, for the treatment and prevention of major types of heart wreckage; coronary, anginal, hypertensive, and rheumatic heart disease; (*Cal-Dex capsules*) to build the body's resistance; and for the treatment and prevention of poor appetite, nervous disturbances, poor digestion, and low resistance to colds and general infections; and (*rectal suppositories*) for the treatment of hemorrhoids.

DISPOSITION: 7-26-63. Default—destruction.

7726. Sure Meal and 2 to 1 food supplement. (F.D.C. No. 48101. S. Nos. 22-394/5 T.)

QUANTITY: 1 drum containing 39 lbs. of *butterscotch-flavored Sure Meal*, 1 drum containing 29 lbs. and 4 15-oz. pkgs. of *chocolate-flavored Sure Meal*, 1 drum containing 59 lbs. and 4 1-lb. 14-oz. pkgs. of *maple mocha Sure Meal*, and 1 drum containing 14 lbs. and 5 15-oz. pkgs. and 2 1-lb. 14-oz. pkgs. of *vanilla-flavored Sure Meal*; 1 drum containing 12,400 mineral tablets, 1 drum containing 980 vitamin tablets, and 15 pkgs., each containing 120 vitamin and 240 mineral tablets, at Salt Lake City, Utah, in possession of Don Lyman & Associates.

SHIPPED: Between 5-14-62 and 9-5-62, from Burbank, Calif., by Teknol Laboratories, Inc.

LABEL IN PART: (Drum) "Manufactured * * * For Don Lyman & Associates * * * (various flavors) Improved Sure Meal Powder Each $\frac{3}{4}$ oz. contains: 60% Protein from non-fat milk solids, soluble collagen and isolated soya protein. * * * Directions: As a dietary supplement"; (pkg.) "Instant Sure Meal (various flavors) will: help you take off weight help you to control weight give you sound nutrition * * * Ingredients: * * * 0.6% sucaryl (sodium cyclamate) (Non-nutritive, artificial sweetener which should be used only by those who wish to restrict the intake of ordinary sweets * * *.) * * * Directions: Mix with a spoon or otherwise three level tablespoons of Sure Meal into 1 cup of milk, hot or cold * * *. You may use Sure Meal in place of your regular meals * * * Weight * * * Manufactured exclusively for Don Lyman and Associates * * * Go The Sure Way"; (drum) "Manufactured * * * For Don Lyman & Associates * * * Mineral Tablets [or "2-1 Vitamin Tablets SC Red"]"; (pkg. top) "Don Lyman's 2 to 1 Food Supplement * * *," (side) "2 to 1 Don Lyman & Associates * * * 1087 East 9th South, Salt Lake City, Utah."

ACCOMPANYING LABELING: Leaflets entitled "Instant Sure Meal"; folders entitled "Never Be Hungry"; and leaflets entitled "Don Lyman's 2 to 1 Food Supplement For That Buoyant Feeling"; as well as additional quantities of repack labels.

RESULTS OF INVESTIGATION: The articles were shipped in bulk drums and were repacked by the dealer. The literature was prepared by the dealer and used for the purpose of promoting sales of the articles.

LIBELED: 9-21-62, Dist. Utah.

CHARGE: *Sure Meal*, 502(a)—while held for sale, the labeling of the article (bulk and repack) contained false and misleading representations that the

article was adequate and effective to reduce, while never being hungry; to gain and control weight; to feel better, promote health, development, and growth; to rebuild tissues; that one serving ($\frac{3}{4}$ oz.) of the article, when mixed with 1 cup of milk, was the nutritional equivalent of a complete meal consisting of meat, vegetables, bread and butter, and a beverage; that the article furnished well balanced, concentrated nutrition in an amount which was low in calories.

2 to 1 food supplement, 502(a)—when shipped, the labeling of the article (bulk and repack) contained false and misleading representations that the article was adequate and effective for the treatment and prevention of headache, nervousness, insomnia, indigestion, diarrhea, constipation, cramps or spasms, anemia, fatigue, and brittle fingernails; to promote buoyant feeling, pep and vitality, and resistance to ordinary infection; and that the article was of significant value for special dietary supplementation by reason of the presence therein of dulse powder, kelp, Irish moss, hyssop, sassafras, elm bark, prune concentrate, malt extract, red bone marrow, betaine, rice polishings, pectin, cellulose complex, papain, watercress concentrate, alfalfa concentrate, parsley concentrate, cabbage concentrate, lecithin, wheat germ concentrate, lemon juice concentrate, rose hips concentrate, hesperidin (citrus bioflavonoids), liver (desiccated), rutin (buckwheat), biotin, para-aminobenzoic acid, choline bitartrate, and inositol.

DISPOSITION: 3-4-63. Default—destruction.

7727. La Lanne protein wafers. (F.D.C. No. 47214. S. No. 30-518 T.)

QUANTITY: 526 cases, each containing 12 360-tablet btl., at Los Angeles, Calif., in possession of La Lanne, Inc.

SHIPPED: Between 9-5-61 and 12-8-61, from Cleveland, Ohio, by Strong, Cobb, Arner, Inc.

LABEL IN PART: (Btl.) "La Lanne Protein Wafers * * * Use with Jack La Lanne's plan of exercise and proper eating * * * Ingredients: An organic food source of natural protein * * * La Lanne Incorporated, 5338 Hollywood Blvd., Hollywood 27, Calif."

ACCOMPANYING LABELING: Booklets entitled "Your Figure By Jack La Lanne."

LIBELED: 3-12-62, S. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective to lose weight, to gain weight, to appear more youthful, to become more healthful, and to have a more attractive figure; and that the article was of significant value for special dietary supplementation as a source of natural and organic protein.

DISPOSITION: 1-25-63. Default—destruction.

7728. Tegrin. (F.D.C. No. 48255. S. Nos. 66-474 T, 22-526 V.)

QUANTITY: 22 $\frac{1}{4}$ cases, each case containing 12 display-type ctns., each ctn. containing 1 tube, at Denver, Colo.

SHIPPED: Between 5-8-62 and 8-10-62, from Jersey City, N.J., by Block Drug Co., Inc.

LABEL IN PART: (Ctn.) "Tegrin For Psoriasis * * * Active Ingredients: Allantoin and a specially-refined extract of coal tar. Tegrin Division, Block Drug Co., Inc., Jersey City 2, New Jersey. Net Wt. 2 Oz."

ACCOMPANYING LABELING: Booklet entitled "A Report: How Science Offers New Help For Psoriasis" (business reply postcards are inserted in booklets).

LIBELED: 11-1-62, Dist. Colo.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was adequate and effective as a treatment for and preventive and cure of psoriasis.

DISPOSITION: 6-24-63. Default—destruction.

7729. Kleen-Air Deodorizer. (F.D.C. No. 48937. S. No. 59-052 V.)

QUANTITY: 53 cases, 12 btls. each, at Atlantic City, N.J.

SHIPPED: 3-20-63, from North Hollywood, Calif., by Kleen-Air Co.

LABEL IN PART: (Btl.) "Kleen-Air 8 Fl. Oz. Stops odors for one year * * * from cooking, food, stale air, tobacco, smoke, pets or paint. Protects for one year For ammonia and chemical odors, use six or more bottles * * * Kleen-Air Co. North Hollywood, Calif."

ACCOMPANYING LABELING: Leaflet attached to bottles of the article reading in part "Kleen-Air Extra Benefits Kleen-Air helps guard against Airborne Irritants that aggravate Allergies * * *."

LIBELED: 5-1-63, Dist. N.J.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was adequate and effective for guarding against airborne irritants that aggravate allergies, hay fever, sinusitis, cough, and asthma; and that use of the article would enable one to sleep better.

DISPOSITION: 6-7-63. Default—destruction.

7730. Abunda Beauty device. (Inj. No. 465.)

COMPLAINT FOR INJUNCTION FILED: 5-16-63, N. Dist. Calif., against Abunda Products, Inc., San Mateo, Calif., and Joseph Ruffino, president.

NATURE OF BUSINESS: Defendants, Abunda Products, Inc., and Joseph Ruffino, were engaged in the business of promoting the interstate sale and distribution of an article which they designated as "Abunda Beauty Hydro Massage Unit." The article was a plastic cup-shaped device with a water hose attachment and it was represented as effective for bust development.

In conducting their sales promotion of the devices, the defendants used various items of descriptive literature, including a pamphlet entitled "Abunda Beauty . . . New . . . Exciting . . . Revolutionary" and a pamphlet entitled "Abunda Hydro Massage Bosom Beauty." In some instances, the defendants shipped the devices in interstate commerce together with the pamphlets. In other instances, the devices were shipped in interstate commerce without the pamphlets but the defendants caused the pamphlets or other similar literature to be brought into juxtaposition with the devices at destination where the literature was used to induce sales of the devices. The pamphlets and other literature comprised the labeling of the devices.

ALLEGED VIOLATIONS: The labeling of each of the devices contained false and misleading statements which represented and suggested that the device was adequate and effective for awakening and increasing bosom beauty; encouraging bosom perfection; restoring, healing, and revitalizing the tissues of the bosom; increasing circulation of the bust; providing cell nourishment to firm the tissues; and providing an abundant bust through hydrotherapy.

The defendants caused the introduction into interstate commerce, of such devices which were misbranded; and the defendants also caused the above labeling to accompany the devices while they were held for sale after shipment in interstate commerce, which acts resulted in the devices being misbranded.

CHARGE: 502(a)—the labeling of the articles was false and misleading since the labeling represented, suggested, and created the impression that the devices were adequate and effective for the purposes described above, whereas the devices were not effective for such purposes.

DISPOSITION: On 5-17-63, a consent decree of permanent injunction was filed which perpetually enjoined and restrained the defendants from directly or indirectly doing any of the following acts with respect to the device or with respect to any similar device, or with respect to any device intended for similar purposes:

A. Causing to be introduced or delivered for introduction into interstate commerce, any of such devices which was misbranded within the meaning of 502(a) and 502(f) (1) because it—

(1) Was accompanied by the pamphlet entitled "Abunda Beauty . . . New . . . Exciting . . . Revolutionary" or the pamphlet entitled "Abunda Hydro Massage Bosom Beauty"; or

(2) Bore or was accompanied by any written, printed, or graphic matter which represented, suggested, or created the impression that such device was adequate and effective for awakening and increasing bosom beauty; encouraging bosom perfection; restoring, healing, and revitalizing the tissues of the bosom; increasing circulation of the bust; providing cell nourishment to firm the tissues; providing an abundant bust through hydrotherapy; or in any way affecting the size or shape of the bust; or

(3) Failed to state in its labeling all of the diseases, conditions, symptoms, and purposes for which the device was intended to be used and for which it was represented, by any means, to the public; or

B. Causing any act to be done with respect to any of said devices while such device was held for sale after shipment in interstate commerce, which act results in such device being misbranded within the meaning of 502(a) or 502(f) (1)—

(1) By being accompanied by any of the written, printed, or graphic matter specified above; or

(2) By bearing or being accompanied by any written, printed, or graphic matter containing any of the representations or suggestions described above; or

(3) By failing to state in its labeling all of the diseases, conditions, symptoms, and purposes for which such device was intended to be used and for which it was represented, by any means, to the public.

7731. Tribotron Negative Ion Generator device. (F.D.C. No. 48069. S. Nos. 75-551/2 T.)

QUANTITY: 47 devices at Petaluma, Calif., in possession of Tribotron Corp.

SHIPPED: 6-18-62 and 7-5-62, from Norfolk, Va., and Waldorf, Md. These were return shipments.

LABEL IN PART: "Tribotron Negative Ion Generator."

ACCOMPANYING LABELING: Leaflets entitled "Medical science reports new relief from hay fever and air-borne allergies! Tribotron Negative Ion Generator Electrostatic Filter" and "Directions and Guarantee for Your Tribotron."

RESULTS OF INVESTIGATION: The dealer had prepared the accompanying labeling for the purpose of promoting sales of the article. Examination indicated the device to be a portable electrostatic-type negative ion generator and air filter. It consisted of a motor which operated the electrostatic generator and blower wheel. The housing also contained a ½-inch-thick polyurethane filter pad for mechanical filtration. The exhaust grill supported a needlepoint-type ion generator. The housing was sheet metal, approximately 18 x 7 x 9 inches.

LIBELED: 8-28-62, N. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the prevention, treatment, or relief of hay fever, bronchial asthma, airborne allergies, respiratory problems, and irritable depression; that the device was important to health and comfort, since it relieved the retarding effects of tobacco smoke and positive ions on the breathing capacity; reduced airborne pollen and dust; accelerated the respiratory-clearing process; and provided relief from the symptoms of hay fever and similar airborne allergies.

DISPOSITION: 11-26-62. Consent—claimed by Tribotron Corp., of Petaluma, Calif., for relabeling.

7732. Electron-O-Ray. (F.D.C. No. 45877. S. No. 28-675 R.)

QUANTITY: 2 devices at Delano, Minn., and 1 device at Minneapolis, Minn.

SHIPPED: Between 6-1-60 and 7-31-60, from Tiffin, Ohio, by Electronic Instrument, Inc.

LABEL IN PART: (Device) "The Electronic Instrument, Inc., Tiffin, Ohio Model 46."

ACCOMPANYING LABELING: Pamphlets entitled "Manual Electron-O-Ray Model 500."

RESULTS OF INVESTIGATION: Examination indicated the article to be a suitcase-type unit which, on opening, displayed a control panel and detector plates. The control panel contained an array of switches, dials, push-buttons, electrode terminals, and indicator lights. Electronic components within the case formed a power supply, oscillator, and amplifier for the detection and/or operation of hertzian waves.

LIBELED: 5-11-61, Dist. Minn.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was capable of diagnosing or treating disease conditions of the uterine cervix, appendix, thyroid, testes and ovaries, lungs, kidneys, colon, stomach, heart, liver, ears, eyes, teeth, brain, blood, mammary glands, and other disease conditions or indications of disease conditions of the various organs of the body.

DISPOSITION: On 8-24-61, E. F. Baldus, D.C., claimant of the article seized at Minneapolis, Minn., filed an answer denying that the article was misbranded. His answer alleged that the Government was without power to seize the article and that the seizure was contrary to the 4th and 14th Amendments of the United States Constitution and violated Article 1, Section 10 of the Constitution of the State of Minnesota.

Thereafter, the Government and claimant served written interrogatories on each other and subsequently each party filed objections to one or more of the other's interrogatories, and the claimant moved that the Government's interrogatories be suppressed upon the following grounds: "1st. That all of the Interrogatories relate to the operation of a machine which was illegally seized from claimant by libelant and is being kept from him contrary to the due process clause of the 14th Amendment of the Constitution of the United States and of the Constitution of the State of Minnesota. 2nd. That each and all of said Interrogatories are designed as to impose the burden of proof of sustaining the claims of libelant as set forth in its Libel, from the libelant to the claimant. 3rd. That libelant can as readily ascertain the facts it requests from claimant as claimant can."

On 6-11-62, the claimant's motion to suppress was argued before the court; the court gave the claimant 30 days in which to answer the Government's interrogatories and stated that the court would consider, in the meantime, a motion for dismissal of the libel. Thereafter, the claimant served a notice of a motion to dismiss the libel and to grant summary judgment to the claimant. On 9-28-62, the court denied the defendant's motion. Thereafter, the claimant withdrew his answer and, on 6-4-63, a decree of condemnation was entered, providing for the delivery of the devices to the Food and Drug Administration.

7733. Vornado Auto Air Conditioner. (F.D.C. No. 48087. S. No. 32-763 T.)

QUANTITY: 109 individually ctn'd. devices at Phoenix, Ariz.

SHIPPED: Between 4-18-62 and 7-6-62, from Los Angeles, Calif., Dallas, Tex., and Boston, Mass., by Automatic Radio Manufacturing Co., Inc.

LABEL IN PART: (Ctn.) "Negative-Ion Vionizer * * * Vornado Auto Air Conditioner."

ACCOMPANYING LABELING: Leaflets entitled "Negative Ions, Positively Wonderful," "Vornado Auto Air Conditioner with Exclusive Vionizer" (small- and large-size leaflets), "Warranty," and "Installation Instructions."

RESULTS OF INVESTIGATION: Investigation indicated that the device was an automobile air conditioner with corona discharge-type negative ion generator attached. The accompanying labeling had been shipped from Dallas, Tex., for the purpose of promoting sales of the article.

LIBELED: 9-12-62, Dist. Ariz.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was an adequate and effective treatment or preventive of mental sluggishness, physical fatigue, dizziness, headaches, abdominal cramps, blurred vision, hay fever, bronchial asthma, sinusitis, migraine, high blood pressure due to hypertension or nervous tension, irritability, loss of depth perception, highway hypnosis, exhaustion, short temper, and sickness; and that the user would be rejuvenated, refreshed, be more alert, and exhilarated.

DISPOSITION: 7-16-63. Consent—claimed by Automatic Radio Manufacturing Co., Inc., Boston, Mass., and brought into compliance with the law by the destruction of the devices' negative ion generators, and the literature and labeling referring thereto.

7734. Croupaire humidifier. (F.D.C. No. 45884. S. No. 10-360 R.)

QUANTITY: 18 devices at Buffalo, N.Y.

SHIPPED: 3-28-61, from Hatboro, Pa., by Air-Shields, Inc.

LABEL IN PART: "Croupaire Model No. 66 Hatboro, Pa. * * * Croupaire is a trademark of Airshields, Inc. for its home humidifier."

ACCOMPANYING LABELING: Leaflets entitled "Instructions for the Croupaire cool-mist humidifier For Direct Inhalation Therapy" and "Pioneering in Cool Vapor Therapy"; brochures entitled "Moisture - A Will-of-the-Wisp," "A therapeutic fog," and "From Air-Shields * * * to permeate the airways with refreshing, healing moisture"; post cards reading in part "Hospital Therapy At Home! No Heat - No Tent - Therapeutic 'Fog Stream' with the Croupaire T.M. Humidifier."

RESULTS OF INVESTIGATION: The device appeared to be a square-shaped metal and plastic container housing a water reservoir, fan, and vaporizer, with air intake at one end of the box and exhaust at the other end. The only control was an "on-off" switch on the front panel of the device.

LIBELED: 5-17-61, W. Dist. N.Y.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the device was an adequate and effective treatment for permeating the airways with refreshing, healing moisture to overcome croup, asthma, bronchitis, emphysema, pneumonia, and other respiratory disorders; preventing secondary upper respiratory infections, coughs, colds, silicosis, atelectasis, whooping cough, pulmonary abscess, cystic fibrosis, and laryngotracheobronchitis; and to aid in recovery following tonsillectomy, tracheotomy, thoracic surgery, and anesthesia.

DISPOSITION: On 6-12-61, pursuant to stipulation between Air-Shields, Inc., claimant, and the Government, an order was entered for the transfer of the case to the District of Delaware. Thereafter, the claimant withdrew its claim and, on 4-12-63, the court entered a decree of condemnation and ordered that one of the devices be delivered to the Food and Drug Administration and that the other devices be destroyed.

7735. Magnetic bracelets. (F.D.C. No. 47730. S. No. 32-446 T.)

QUANTITY: 999 bracelets at Las Vegas, Nev., in possession of David Ming Stores.

SHIPPED: 10-9-61, from Los Angeles, Calif., by "Chip" Quon, owner of Quon Importing Co.

LABEL IN PART: (Stamped on bracelet) "Super Magic."

ACCOMPANYING LABELING: Window display of a newspaper advertisement, reading in part "Mystery Centuries old oriental health mystery comes to Las Vegas. Oriental Mystic Health Bracelet"; typewritten and printed leaflets, reading in part "Instructions 'magnetic bracelet' For Keep Youth and Health!"

RESULTS OF INVESTIGATION: The dealer had prepared the above newspaper advertisement and had in his possession the window display which consisted of the mounted clipping of the advertisement. The dealer had also made typewritten copies of the above-printed leaflet which had been received from the shipper.

Examination showed that the article was an expansion-type bracelet containing 8 magnetic bars (each about $\frac{1}{2} \times \frac{3}{8} \times \frac{1}{2}$ inches, and separated by 3 or 4 expansion links). A brass-colored, thin metal sheet with decorative design covered the outer surface of each unit in the bracelet, and all other surfaces were plain and silver colored.

LIBELED: 7-17-62, Dist. Nev.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective as a treatment for and as a preventive of high blood pressure, low blood pressure, neuralgia, rheumatism, change of life, stiff shoulders, fatigue, insomnia, headache, hyperacidity of the stomach, diminishing vigor, to promote health, and prevent aging in women from a beauty standpoint.

DISPOSITION: 8-31-62. Default—ordered delivered without the labeling to a charitable institution for purposes of sale in compliance with the law and without the accompanying labeling; the proceeds of sale to be retained by the institution.

7736. Magnetic bracelets. (F.D.C. No. 48045. S. No. 55-514 T.)

QUANTITY: 95 bracelets at Santurce, P.R., in possession of Indochina International.

SHIPPED: 7-16-62, from Miami, Fla., by International Silk & Novelty Corp.

LABEL IN PART: "Made in Japan."

ACCOMPANYING LABELING: Leaflets entitled "Pulsera Magnetica" and "Magnetic Ring."

RESULTS OF INVESTIGATION: The leaflets entitled "Pulsera Magnetica" were printed locally on the order of the dealer and the leaflets entitled "Magnetic Ring" were transported by the dealer from Miami.

Examination showed the article to be a metal expansion-type bracelet composed of 8 slightly magnetic links, each being separated by 3 smaller non-magnetic links.

LIBELED: 9-28-62, Dist. P.R.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective for maintaining one's health and youth; preventing high blood pressure, fatigue, and stiff shoulders; and benefiting the blood and muscles of the body.

DISPOSITION: On 10-10-62, the claimant filed a motion asserting ownership of the article and moving to stay publication of process.

On 10-16-62, Indochina International of Puerto Rico, Inc., filed an answer claiming the article. The claimant's answer prayed that the article not be condemned and that it be delivered back to the claimant which bound itself to eliminate all literature of every kind, and especially all labeling making reference directly or indirectly or representing and suggesting, that the article was adequate and effective for maintaining health or youth; that the article prevented high blood pressure, fatigue, and stiff shoulders; or that the article benefited the blood and muscles of the body. On 10-18-62, the court stayed and suspended publication of process.

On 11-13-62, the Government served a motion for judgment on the pleadings for an order of condemnation and destruction. On 12-14-62, the court granted the Government's motion and entered an order of condemnation and destruction.

7737. Pulse-A-Rythm vibrating mattress. (F.D.C. No. 48263. S. No. 2-212 V.)

QUANTITY: 1 device at Smyrna, Ga.

SHIPPED: 9-29-62, from St. Petersburg, Fla., by Silent Daddy Corp.

LABEL IN PART: (Label on mattress) "Pulse-A-Rythm Massaging Mattress Exclusive Product of Pulsnation Enterprises, St. Petersburg, Florida."

ACCOMPANYING LABELING: Pamphlet entitled "For the Best of Rest"; testimonial letters to Pulsnation Enterprises, Inc., dated Nov. 10, 1960 signed "Lucille A. Heiser," and dated July 24, 1962 from Mr. Theodore K. Quinn, Jr.; pamphlets entitled "This to This—Thru This (Pictures) Silent Daddy Pulsating Crib Mattress" and "Exclusive Features List 1. * * * 2. Completely treated with special residual germicide"; a magnetic tape containing a message from Raymond Whitmore, president of the Silent Daddy Corp.; stamped self-addressed envelope addressed to "Mr. Kenneth H. Fricker, Silent Daddy Corporation * * * St. Petersburg, Florida"; retail installment contract, No. 1113, undated, and carbon copy of the contract; business card of Kenneth H. Fricker; pamphlet entitled "For the Best of Rest * * * Pulsnation Enterprises, Inc. * * * Distributed by Kenneth Fricker Silent Daddy Corporation"; and business reply card addressed "Silent Daddy Corp." stapled to a pamphlet reading in part "So heavenly soft—yet so healthfully firm * * * completely treated with special residual germicide to aid in the prevention of communicable diseases."

RESULTS OF INVESTIGATION: Examination indicated that the article was essentially a spring-filled mattress, one end of which enclosed an electric motor attached to an off-center shaft which provided a vibratory action. The enclosed unit included a timer and a rheostat.

LIBELED: 10-30-62, N. Dist. Ga.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the correction of conditions of arthritis, bursitis, rheumatism, and poor circulation and related disorders; that it relaxed and soothed pain in legs from nerve pressure; relieved the tensions causing severe migraine; cured chronic insomnia; alleviated headaches; and helped heart conditions.

DISPOSITION: 12-13-62. Default—ordered delivered to a charitable institution, provided that the small motor contained in the article was removed prior to delivery.

7738. Relax-A-Matic Massage Assembly Units. (F.D.C. No. 48411. S. No. 74-668 T.)

QUANTITY: 7 ctnd. assembly unit devices, 11 demonstration pillows, 1 coin-operated timer, 1 ctnd. music minder, and 1 ctnd. timing device, at New York, N.Y.

SHIPPED: During December 1961, from East Orange, N.J., by Relax-A-Matic.

LABEL IN PART: (Ctn.) "For the 'Rest' of Your Life * * * Relax-A-Matic Automatic massage Assembly Unit Model M5 * * * Serial No. * * * Instructions Enclosed"; (pillow tag) "Relax-A-Matic * * * by Vita-Rest Health Products Co."; (device) "Meter Magic * * * (coin operated timer)"; (ctn.) "Intermatic Music Minder Model A501"; (ctn.) "Mark-Time Timing."

ACCOMPANYING LABELING: One set of operational instructions, assembly instructions, and registration card in each carton of the assembly units, and undetermined quantities of the following: 29-page leaflet entitled "Vita Rest Corporation Helpful Sales Suggestions Explanation of Sales Methods"; single sheet entitled "Lease Agreement"; 100-page sales book entitled "Relax-a-Matic of No. * * * Distributor's Copy"; business reply card addressed to "Relax-A-

Matic Vita-Rest Health Products, Inc. * * * East Orange, New Jersey"; registration card reading in part "Important * * * Mail this Card Now!"; reprints entitled "Super-Motels * * * Reproduced from Wall Street Journal August 18, 1954," "Special Mattress Gift to Hospital * * * from the Omaha World-Herald August 7, 1952," and "Motel The 'How To' Magazine of Motel Management * * * Relax-a-Matic By Vita-Rest Health Products, Inc., 105 Halsey Street-Newark 2, N.J."; single sheet entitled "Wonders of the Heart"; single sheet entitled "The Best Things In Life Cost Money"; leaflet entitled "Research scientists are developing the knowledge needed to prevent and control heart disease. Here's what you can do . . ."; and card reading in part "Notice This Bed is Equipped With the Famous Relax-A-Matic Massaging Mattress."

RESULTS OF INVESTIGATION: The article consisted of a variety of pillow, coin-operated and electric timers, and pulsating motors enclosed in a metal cup with adjustable arms attached for mounting to bedsprings.

LIBEL: 12-17-62, S. Dist. N.Y.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the article was adequate and effective as a treatment for varicose veins, rheumatic fever, heart disease, heart attacks, arthritis, poor circulation, lumbago, gout, aches and pains, soreness, stiffness, back and sacroiliac pain, nervousness, hypertension, insomnia, headaches, rheumatism, pains, hay fever, asthma, sinus, indigestion, nervous attacks, and high blood pressure; and that use of the article would relax the heart; keep veins and arteries free from deposits; act as a tranquilizer, sleeping pill, analgesic, and laxative; control weight; and rebuild the body.

DISPOSITION: 4-16-63. Consent—claimed by Andrew Weiss, Brooklyn, N.Y., and ordered released under bond to be brought into compliance with the law.

7739. Massage Master device and attachments. (F.D.C. No. 47702. S. No. 32-481 T.)

QUANTITY: 1,495 devices with attachments, at Huntington Park and Los Angeles, Calif., in possession of Masterade of America, Inc.

SHIPPED: 5-18-61 and 5-12-61, from Sterling, Ill.

LABEL IN PART: "Massage Master Model VII Masterade of America Inc. Huntington, Calif."

ACCOMPANYING LABELING: Booklets entitled "Massage Master Presentation & Demonstration Guide"; instruction manual entitled "Massage Master" with inserts; card reading in part "A representative * * * will call"; business reply card entitled "Good for Free Tide"; and picture leaflet entitled "Massage Master."

RESULTS OF INVESTIGATION: Examination showed that each article consisted of 1 electrical device and 4 attachments. The device had a two-piece, black plastic covering which housed the electrical system. The overall shape was that of a short club; the greatest length was $9\frac{1}{4}$ inches; the blunt end measured about $3\frac{3}{4}$ inches wide and $\frac{5}{16}$ to $2\frac{1}{4}$ inches thick; and the handle portion measured about 1 inch wide and 1 inch thick. At the blunt end there was a cylindrical metal projection which fitted into the attachments. At the handle end there was a gray electric cord. A white plastic switch was located at the center of the device. Three of the attachments were made of soft, synthetic rubber and one was made of hard plastic, all being made to fit onto the device. The attachments were designated in the instruction book as

"Beauty Cup," "Body and Foot Massager" (the hard plastic), "All Purpose Massager," and "Scalp-O-Lator." Each device was enclosed in a case with the various attachments and the instruction manual. The dealer had prepared and had printed locally, the accompanying labeling for use in promoting sales of the article.

LIBELED: 7-5-62, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the accompanying labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for ailments of the nerves, muscles, skin, vascular system, entire body structure, and physiological processes; throbbing headaches due to tension; tiredness; nervousness; insomnia; indigestion; constipation; colds and bronchial conditions; eye strain; sinus congestion; improving nutrition of muscles; improving respiration; improving bones; invigorating digestion; arousing nerve force; equalizing circulation; eliminating organic wastes and fatigue products; stimulating reflex action of the nerves; and speeding up blood circulation.

DISPOSITION: 9-24-62; amended decree 10-25-62. Default—18 devices and their accompanying labeling delivered to the Food and Drug Administration and the remainder destroyed.

DRUG FOR VETERINARY USE*

7740. Prescription No. H-525. (F.D.C. No. 46736. S. No. 13-901 R.)

QUANTITY: 10 120-lb. drums at Mendota, Ill.

SHIPPED: 6-13-61, from Charles City, Iowa, by Dr. Mayfield Laboratories.

LABEL IN PART: "O. J. Mayfield, D.V.M. Charles City, Iowa Prescription No. H-525 For Rhinitis in Hogs * * * This Product Contains Arsenic Poison * * * Caution * * * Fasco Mills Co. Mendota, Illinois."

RESULTS OF INVESTIGATION: Analysis of the article showed it be a finely ground reddish-colored material containing approximately 1 percent arsenic compound.

LIBELED: 11-20-61, N. Dist. Ill.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for the control and prevention of rhinitis in hogs; and 502(e) (2)—the label of the article failed to bear the common or usual name of the arsenical present as the active drug ingredient.

DISPOSITION: On or about 1-17-62, the case was transferred to the Southern District of Iowa. Thereafter, the claimant, Dr. Mayfield Laboratories, Inc., Charles City, Iowa, filed an answer denying that the article was misbranded. On or about 3-30-62, interrogatories were served upon the defendants and, on 5-5-62, the claimant served answers to the Government's interrogatories. On 2-18-63, a decree of condemnation was entered, which was amended on 2-27-63, to order destruction of the article. The article was destroyed.

*See also Nos. 7688, 7707, 7718, 7719.

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¹(7687, 7692, 7694, 7697, 7698, 7730) Injunction issued.²(7681) Seizure contested. Injunction issued.³(7721, 7722, 7740) Seizure contested.⁴(7702, 7711, 7732) Seizure contested; request for summary judgment.⁵(7689) Prosecution contested. Contains memorandum opinion and order of the court.

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Phyl-In Alfa tablets.....	7720	Super-Coronaids tablets.....	³ 7721
Prescription drugs.....	7682, 7690, 7691	Super-Kalvita-Plus capsules.....	7725
Prescription No. H-525.....	³ 7740	Sure Meal, butterscotch-flavored,	
Procaine penicillin G suspen-		chocolate-flavored, maple mo-	
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Prophylactics, rubber.....	7714-7717	Taylor's, Dr., Special Formula	
Protein wafers, La Lanne.....	7727	L	² 7681
Psoriasis, remedy for.....	7728	Tegrin	7728
Pulse-A-Rythm vibrating mat-		Tribotron Negative Ion Genera-	
tress	7737	tor device.....	7731
Rectal suppositories.....	7725	2 to 1 food supplement.....	7726
Reducing preparation.....	¹ 7694	Vac-U-Prep device.....	7701
Relax-A-Matic Massage Assembly		Vacuum cleaner, Filter Queen,	
Units	7738	and accessory devices and at-	
Rheumatism, remedies for (de-		tachments	¹ 7697
vices)	¹ 7697, 7737	Vegetable Seasoning.....	¹ 7692
(drug)	7696	Veterinary preparations....	7685, ¹ 7687,
Ritran tablets	7724	7688, 7706, 7707, 7718, 7719, ³ 7740	
Rysal tablets.....	7695	Virac Rex solution.....	7684
Safflower oil capsules.....	7723	Vi-Ron-Ite tonic.....	7712
Scholl's, Dr., Foot Exercizer San-		Vitamin preparations..	7692, ⁴ 7711, 7712
dals	7700	Vornado Auto Air Conditioner..	7733
Sciatica, remedies for. <i>See</i>		Water softener devices and com-	
Rheumatism, remedies for.		ponents, automatic and port-	
Secobarbital sodium capsules....	⁵ 7689	able	¹ 7698
Serpasil tablets, imitation.....	7709		

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

	N.J. No.		N.J. No.
Abt, Dr. W. L.:		Abunda Products, Inc.:	
various drugs.....	¹ 7692	Abunda Beauty device.....	¹ 7730
Abtco Distributors:		Air-Shields, Inc.:	
various drugs.....	¹ 7692	Croupaire humidifier.....	7734

¹(7687, 7692, 7694, 7697, 7698, 7730) Injunction issued.²(7681) Seizure contested. Injunction issued.³(7721, 7722, 7740) Seizure contested.⁴(7702, 7711, 7732) Seizure contested; request for summary judgment.⁵(7689) Prosecution contested. Contains memorandum opinion and order of the court.

	N.J. No.		N.J. No.
Allied Latex Sales Co., Inc.:		Diamond Laboratories:	
rubber prophylactics-----	7714	procaine penicillin G suspen-	
Automatic Radio Manufacturing		sion -----	7688
Co., Inc.:		<i>See also</i> United Veterinary	
Vornado Auto Air Condi-		Corp.	
tioner -----	7733	Donley-Evans & Co.:	
Balanced Foods, Inc.:		Lipo-Cylate solution-----	7696
Super-Coronaïd tablets-----	7721	Drug Research Corp.:	
Barnett Distributing Co.:		Insta-Pep tablets-----	⁴ 7711
rubber prophylactics-----	7714	Eastern Grain Co.:	
Barnetts, Inc.:		medicated feed-----	7718
rubber prophylactics-----	7714	Electronic Instrument, Inc.:	
Beasley, Herb:		Electron-O-Ray -----	7732
Filter Queen vacuum cleaner		Ellis Research Laboratories,	
and accessory devices and at-		Inc.:	
tachments -----	¹ 7697	Micro-Dynameter devices_	7702-7705
Block Drug Co., Inc.:		Encapsulations, Inc.:	
Tegrin -----	7728	safflower oil capsules-----	7723
<i>See also</i> Tegrin Div.		Endocrine Research Labora-	
Brown, Dwight L., Enterprises:		tories:	
Vi-Ron-Ite tonic-----	7712	Liefcort -----	7683
Bundy, C. M., Co.:		Fasco Mills Co.:	
various drugs-----	7708	Prescription No. H-525-----	7740
Vi-Ron-Ite tonic-----	7712	Fifth Avenue Pharmacy. <i>See</i>	
Chamberlin Natural Foods:		Treiman Drugs, Inc.	
Super-Coronaïd tablets-----	7721	Filter Queen, Inc.:	
Consolidated Laboratories, Inc.:		Filter Queen vacuum cleaner	
Multidisk Sensitivity Discs---	7686	and accessory devices and at-	
Cowley Pharmaceuticals, Inc.:		tachments -----	¹ 7697
sodium para-aminosalicylic		Fleetwood Co.:	
acid tablets-----	7713	Larson's C.R.D. food supple-	
Craig, L. B.:		ment -----	¹ 7694
imitation Dexedrine Sulfate		Halsey Drug Co.:	
tablets and imitation Serpa-		safflower oil capsules-----	7723
sil tablets-----	7709	Health-Mor, Inc.:	
Craig Drug Co. <i>See</i> Craig, L. B.		Filter Queen vacuum cleaner	
Crosby Milling Co., Div. of Cutler		and accessory devices and at-	
Co.:		tachments -----	7697
medicated feed-----	7718	Hynes Pharmacy:	
Cutler Co. <i>See</i> Crosby Milling		various prescription drugs----	7690
Co.		Illinois Herb Co.:	
Darnaud, Ray:		Super-Kalvita-Plus capsules,	
automatic and portable water		Cal-Dex capsules, and rectal	
softener devices and compo-		suppositories -----	7725
nents -----	¹ 7698	Indochina International:	
Davis Professional Drugs:		magnetic bracelets-----	7736
various prescription drugs----	7682	International Silk & Novelty	
Dean Rubber Manufacturing Co.:		Corp.:	
rubber prophylactics-----	7715-7717	magnetic bracelets-----	7736

¹(7687, 7692, 7694, 7697, 7698, 7730) Injunction issued.⁴(7702, 7711, 7732) Seizure contested; request for summary judgment.

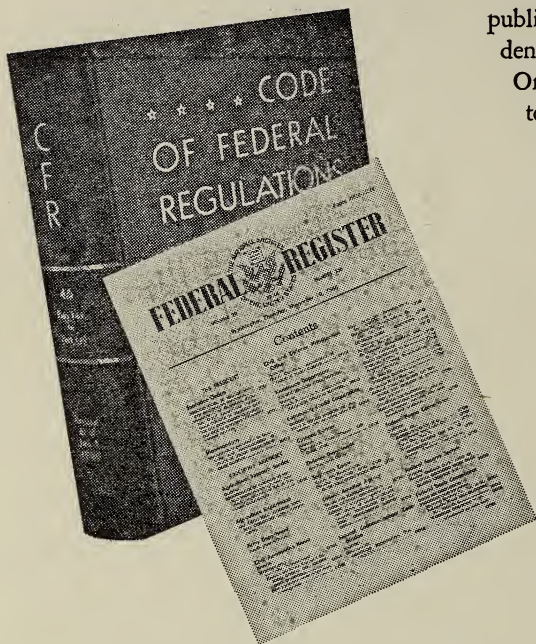
	N.J. No.		N.J. No.
Johns Distributing Co.:		Minnesota Pharmaceutical Laboratories, Inc.:	
Davis Union Remedy laxative and component materials---	³ 7722	Rysal tablets-----	7695
Justice, R. S.:		Noble-Blackmer, Inc.:	
various drugs-----	7708	nitroglycerin digitalis compound tablets-----	7708
Kenyon Vet Supply:		Noble Massey Co.:	
Milk-A-Way Minerals with Sulphas-----	7707	Ritran tablets-----	7724
Kiss, Louis:		Nutri-Bio Corp.:	
Nutri-Bio food supplement----	7693	Nutri-Bio food supplement----	7693
Kleen-Air Co.:		Oesterling, P. J., & Son, Inc.:	
Kleen-Air Deodorizer-----	7729	medicated feed-----	7719
Lafayette Pharmacal, Inc.:		Ogden Grain Co., Inc.:	
ergonovine maleate tablets----	7708	medicated feeds----- ¹	7687, 7706
La Lanne, Inc.:		Paine Drug Co., The:	
La Lanne protein wafers----	7727	Special Formula No. 3-12890 tablets-----	7708
Lindsay Co., The:		Palmedico, Inc.:	
automatic and portable water softener devices and components-----	¹ 7698	Lipo-Cylate solution-----	7696
Lindsay Soft Water Co., Inc.:		Pan American Laboratories:	
automatic and portable water softener devices and components-----	¹ 7698	heifer and steer implants----	7685
Lustgarten Laboratories:		Papak, H. S.:	
safflower oil capsules-----	7723	dextro-amphetamine sulfate capsules, secobarbital sodium capsules, meprobamate tablets, imitation Diuril tablets, and imitation Hydrodiuril tablets-----	⁵ 7689
Lyman, Don, & Associates:		Preston-National Drug Co.:	
Sure Meal and 2 to 1 food supplement-----	7726	Dr. Taylor's Special Formula L-----	7681
Masterade of America, Inc.:		Professional Pharmacy #2:	
Massage Master device and attachments-----	7739	various prescription drugs----	7691
Maury Biological Co., Inc.:		Pulsnation Enterprises:	
penicillin drugs-----	7710	Pulse-A-Rythm vibrating mattress-----	7737
procaine penicillin G suspension-----	7688	Quon, "Chip":	
Mayfield, O. J.:		magnetic bracelets-----	7735
Prescription No. H-525-----	³ 7740	Quon Importing Co.:	
Mayfield, Dr., Laboratories:		magnetic bracelets-----	7735
Prescription No. H-525-----	³ 7740	Relax-A-Matic:	
Millpax:		Relax-A-Matic Massage Assembly Units-----	7738
Millrue Iron Tonic-----	7720		
Ming, David, Stores:			
magnetic bracelets-----	7735		

¹(7687, 7692, 7694, 7697, 7698, 7730) Injunction issued.³(7721, 7722, 7740) Seizure contested.⁵(7689) Prosecution contested. Contains memorandum opinion and order of the court.

	N.J. No.		N.J. No.
Roberts, W. H.:		Treiman Drugs, Inc.:	
Millrue Iron Tonic, Soy Germ		dextro-amphetamine sulfate	
Oil tablets, and Phyl-In Alfa		capsules, secobarbital sodi-	
tablets -----	7720	um capsules, meprobamate	
Roberts Health Center. See		tablets, imitation Diuril tab-	
Roberts, W. H.		lets, and imitation Hydro-	
Ruffino, Joseph:		diuril tablets-----	⁵ 7689
Abunda Beauty device-----	¹ 7730	Tribotron Corp.:	
Ruson Laboratories, Inc.:		Tribotron Negative Ion Genera-	
Virac Rex solution-----	7684	tor device-----	7731
St. Albans Grain Co.:		U.S. Nutrition Products Co.:	
medicated feed-----	7718	Super-Coronaide tablets-----	³ 7721
Scholl Manufacturing Co., Inc.:		United Veterinary Corp.:	
Dr. Scholl's Foot Exercizer		procaine penicillin G suspen-	
Sandals -----	7700	sion -----	7688
Silent Daddy Corp.:		United Whelan Corp.:	
Pulse-A-Rythm vibrating mat-		safflower oil capsules-----	7723
tress -----	7737	Vita-Rest Health Products Co.:	
Sooner Prosthetics, Inc.:		Relax-A-Matic Massage Assem-	
Vac-U-Prep device-----	7701	bly Units-----	7738
Strong, Cobb, Arner, Inc.:		Walgreen Drug Co.:	
La Lanne protein wafers-----	7727	Larson's C.R.D. food supple-	
Taylor, Dr. G. E.:		ment -----	¹ 7694
heifer and steer implants----	7685	Walgreen Drug Stores:	
Taylor Clinic:		Larson's C.R.D. food supple-	
Dr. Taylor's Special Formula		ment -----	¹ 7694
L -----	² 7681	Wargell, W. F.:	
Tegrin Div., Block Drug Co.,		various drugs-----	7708
Inc.:		Whelco Products, Inc.:	
Tegrin -----	7728	safflower oil capsules-----	7723
Teknol Laboratories, Inc.:		Wirthmore Feeds, Inc.:	
Sure Meal and 2 to 1 food sup-		medicated feed-----	7718
plement -----	7726	York Barbell Co.:	
Treiman, L. L.:		Soy Germ Oil tablets-----	7720
dextro-amphetamine sulfate		Yosemite Veterinary Hospital &	
capsules, secobarbital sodi-		Supply:	
um capsules, meprobamate		heifer and steer implants----	7685
tables, imitation Diuril tab-			
lets, and imitation Hydro-			
diuril tablets-----	⁵ 7689		

¹(7687, 7692, 7694, 7697, 7698, 7730) Injunction issued.²(7681) Seizure contested. Injunction issued.³(7721, 7722, 7740) Seizure contested.⁵(7689) Prosecution contested. Contains memorandum opinion and order of the court.

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U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

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[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act] 8 1964

7741-7780

DRUGS AND DEVICES

CURRENT SERIAL RECORDS

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were alleged to be adulterated or misbranded, or otherwise violative of the Act, when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent, including, in one case, the entry of a consent decree of permanent injunction; and (2) criminal proceedings which were terminated upon pleas of guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., September 16, 1964.

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*For drugs actionable because of insanitary conditions, see No. 7750; omission of, or unsatisfactory, ingredients statements, Nos. 7745, 7768; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 7745, 7749; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 7745, 7749; cosmetics actionable under the drug provisions of the Act, Nos. 7768, 7769, 7778.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN ALLEGED VIOLATIONS REPORTED IN D.D.N.J. NOS. 7741-7780

Adulteration, Section 501 (a) (2) (A), the article had been held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its quality and purity fell below the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess; and Section 501 (d) (2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502 (e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient contained therein; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (1), the article was composed wholly or in part of a kind of penicillin, streptomycin, chlortetracycline, or some derivative thereof and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; Section 503 (b) (1), the article was a drug intended for use by man which, because of its toxicity or other potentiality for harmful effect, or the collateral measures necessary to its use, was not safe for use except under the supervision of a practitioner licensed by law to administer such drug, and it was dispensed contrary to the provisions of this Section; and Section 503 (b) (4), the article was a drug subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription," or the article was a drug to which Section 503 (b) (1) did not apply and at a time prior to dispensing its label bore the quoted preceding caution statement.

New-drug violation, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an approval of an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

7741. Pentaerythritol tetranitrate capsules. (F.D.C. No. 48745. S. No. 54-788 V.)

QUANTITY: 6,250 capsules in 1,000-capsule btl., at Mechanicsville, Iowa.

SHIPPED: 3-7-63, from St. Louis, Mo., by Shaw Pharmacal Co.

LABEL IN PART: (Btl.) "Penta-Cap No. 2 * * * each capsule contains Pentaerythritol Tetranitrate 60 Mg. * * * Manufactured for Kenyon Drug Co. Mechanicsville, Iowa."

RESULTS OF INVESTIGATION: The article had been shipped in bulk drums and had been repacked into bottles by the dealer.

LIBELED: 4-11-63, N. Dist. Iowa.

CHARGE: 505(a)—when shipped, the article was a new drug within the meaning of the law, and no approval of an application was effective with respect to such article.

DISPOSITION: 5-16-63. Default—destruction.

7742. Cruzylan products. (F.D.C. No. 48245. S. Nos. 42-153/6 T.)

QUANTITY: 994 40-cc. ctnd. btl. of *Mundtropfen*, 492 10-cc. ctnd. btl. of *Cruzylanid A*, 484 10-gm. ctnd. tubes of *Cruzylanid B*, and 994 1-oz. ctnd. tubes of *Cruzylan*, at Philadelphia, Pa.

SHIPPED: 7-5-60 and 8-8-60, from Munich, Germany, by Primus-Produktion.

LABEL IN PART: (Ctn.) "Cruzylan Mundtropfen * * * Hersteller: Primus-Produktion Muchen 58" and "Cruzylanid A coadiuvante nel trattamento della Piorrea Alveolare * * * Prodotto in Germania dalla Primus Produktion-Monaco Di Baviera"; (btl. and tube) "Cruzylanid A [or "B"] nach Prof. Dr. med Gins * * * Primus-Produktion Muchen 58"; (ctn.) "Cruzylanid B * * * Prodotto in Germania dalla Primus Produktion-Monaco di Baviera"; (ctn. and tube) "Cruzylan Del Professor Dr. H. A. Gins Instituto Robert Koch, Berlino * * * Composizione: * * * prodotto in Germania dagli Stubilimenti Primus-Monaco"; and sticker labels reading "Caution—New Drug Limited By United States Law To Investigate Use" or "Limited by U.S.P. Law For Investigational Use Only."

ACCOMPANYING LABELING: Carton inserts entitled "Cruzylan the unique effective quick-acting remedies against parodontitis spirillosa and similar diseases," "Cruzylanid A and Cruzylanid B," and "Cruzylan gli unici rimedi di sicura ed immediata efficacia contro."

LIBELED: 10-23-62, E. Dist. Pa.

CHARGE: 505(a)—the articles were new drugs which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to law was effective with respect to such drugs.

DISPOSITION: 11-21-62. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE FOR WHICH NONE HAD BEEN ISSUED

DRUGS FOR HUMAN USE

7743. Sigmamicina capsules and penicillin for injection. (F.D.C. No. 48804. S. Nos. 39-968 V, 39-970 V.)

QUANTITY: 43 cases, each containing 48 8-capsule btl., of *Sigmamicina*, and 2 drums, each containing 25 unlabeled plastic bags of *penicillin for injection*, at Hato Rey, P.R., in possession of Pfizer Corp.

SHIPPED: Between 8-11-62 and 8-16-62, from New York, N.Y.

LABEL IN PART: (Btl.) "Sigmamicina con glucosamina 250 mg. Cada capsula contiene 250 mg. de Sigmamicina (83 mg. de oleandomicina en forma de oleandomicina triacetilada y 167 mg. de clorhidrato de tetraciclina con glucosamina) * * * Chas. Pfizer & Co. Inc., New York, New York"; (tag label in drum) "Pfizer Penicillin G Procaine Crystalline with Buffered Penicillin G Potassium Crystalline For Aqueous Injection Units 25,000,000,000 * * * Caution * * * Chas. Pfizer & Co., Inc. * * * New York."

RESULTS OF INVESTIGATION: The *Sigmamicina capsules* had been shipped in bulk containers and had been repacked by the dealer into bottles. The *penicillin*

for injection had been shipped in bulk drums, each drum containing one plastic bag, containing 25,000,000,000 units of the article, and it had been subsequently shipped from Hato Rey, P.R., to Carolina, P.R., where it was repacked into the 25 unlabeled plastic bags in each drum and then had been returned to the dealer.

LIBELED: 3-29-63, Dist. P.R.

CHARGE: 502(1)—while held for sale, the *Sigmamicina capsules* were composed wholly or in part of a derivative of chlortetracycline and the *penicillin for injection* of a kind of penicillin, and the articles were not from batches with respect to which certificates or releases issued pursuant to 507 were effective.

DISPOSITION: 4-26-63. Consent—claimed by Pfizer Corp. and brought into compliance with the law by certification.

DRUGS FOR VETERINARY USE

7744. Procaine penicillin. (F.D.C. No. 49235. S. Nos. 6-730 X, 6-733 X.)

QUANTITY: 13 cases, each containing 25 100-cc. vials of *procaine penicillin in crystalline dihydrostreptomycin solution*, and 19 cases, each containing 25 100-cc. vials of *procaine penicillin in aqueous solution*, at Millbury, Mass.

SHIPPED: 5-3-63 and 5-9-63, from Norwich, Conn., by Masti-Kure Products Co., Inc.

LABEL IN PART: (Vial) "Pen-Strep Procaine Penicillin in Crystalline Dihydrostreptomycin Solution * * * For Veterinary Use Only * * * Distributed by Independent Buyers Association, Millbury, Mass.," and "300,000 u/cc Penicillin G U.S.P. Procaine Penicillin in Aqueous Solution * * * For Veterinary Use Only * * * Independent Buyers Association, Millbury, Mass."

LIBELED: 8-22-63, Dist. Mass.

CHARGE: 502(1)—when shipped, the articles purported to be and were represented as drugs composed wholly or in part of procaine penicillin and dihydrostreptomycin, and they were not from batches with respect to which certificates or releases issued pursuant to law were in effect.

DISPOSITION: 10-29-63. Consent—claimed by Masti-Kure Products Co., Inc.; 19-case lot relabeled and 13-case lot destroyed.

VIOLATIVE SALE OF PRESCRIPTION DRUG

7745. Amphetamine sulfate tablets. (F.D.C. No. 49176. S. Nos. 87-815/17 T, 6/9 V.)

INFORMATION FILED: 10-1-63, W. Dist. S.C., against Frank Albert Mays, a truck stop operator, Reidsville, N.C.

ALLEGED VIOLATIONS: On 8-29-62, while bags of *amphetamine sulfate tablets* were being held for sale at a place between Greenville and Greer, S.C., after shipment in interstate commerce, the defendant caused the article to be dispensed without a prescription, which act resulted in the article being misbranded.

On 10-25-62, while drums of *amphetamine sulfate tablets* were being held for sale after shipment in interstate commerce, the defendant caused the article to be held for sale in unlabeled drums, which act resulted in the article being misbranded.

CHARGE: Bags of *amphetamine sulfate tablets*, 503(b) (1)—while held for sale, the article was dispensed without a prescription.

Drums of *amphetamine sulfate tablets*, 502(b) (1)—while held for sale, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(b) (2)—the article failed to bear a label containing an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; 502(e) (1)—the article failed to bear the common or usual name of the drug; 502(f) (1)—the labeling of the article failed to bear adequate directions for use and the drug was not exempt from such requirement of adequate directions for use, since the drug was a prescription drug in the possession of the defendant who was not regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs; and 503(b) (4)—the article was a drug subject to 503(b) (1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

PLEA: Guilty.

DISPOSITION: 10-29-63. 12 months in prison.

DRUG IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

7746. Per-Versa prenatal dietary supplements. (F.D.C. No. 48719. S. No. 38-041 V.)

QUANTITY: 13 cases, each containing 24 100-tablet btls., at New Orleans, La.

SHIPPED: 3-6-61, from St. Louis, Mo., by Shaw Pharmacal Co.

LABEL IN PART: (Btl.) "Pre-Versa Prenatal Vitamin-Mineral Dietary Supplements for use in prenatal care and lactation * * * manufactured for Roberts Pharmaceuticals Inc. New Orleans, La. each 3 tablets contain * * * Vitamin D, 900 USP Units * * * Vitamin C, 75 MG. * * * Vitamin B₁, 1.125 MG. Caution: Federal Law Prohibits Dispensing without a prescription."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 60 percent vitamin D, 60 percent vitamin C, and 72 percent vitamin B₁ of the declared amounts of these vitamins.

LIBELED: 3-8-62, E. Dist. La.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; 502(a)—the label statements "Vitamin D, 900 USP Units," "Vitamin C, 75 MG." and Vitamin B₁, 1.125 MG." were false and misleading; and 503(b) (4)—when shipped, the drug was not subject to the provisions of 503(b) (1) and its label bore the statement "Caution: Federal Law Prohibits Dispensing without a prescription."

DISPOSITION: 7-24-63. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

7747. Amphetamine-containing drugs and barbiturate-containing drugs. (F.D.C. No. 48984. S. Nos. 5-391/400 V, 69-561 V.)

QUANTITY: *Amphetamine-containing drugs* and *barbiturate-containing drugs* consisting of a total of approximately 602,356 tablets and capsules at Baltimore, Md., in possession of Reyman Drug Co., Inc.

*See also No. 7745.

SHIPPED: Prior to 5-23-63, from outside the State of Maryland.

LIBELED: 5-23-63, Dist. Md.

CHARGE: 502(f) (1)—while held for sale, the labeling of the articles failed to bear adequate directions for use, and the articles were not exempt from such requirement since the articles were in the possession of a person who was not lawfully engaged in the manufacture, transportation, storage, or distribution of prescription drugs, and since such articles were not to be dispensed upon prescription.

DISPOSITION: 7-8-63. Default—the articles were ordered to be destroyed or delivered to the Food and Drug Administration.

7748. Multiglands injection. (F.D.C. No. 49229. S. No. 39-981 X.)

QUANTITY: 416 individually ctn'd. 30-cc. vials, at Brooklyn, N.Y.

SHIPPED: Between 11-14-62 and 6-21-63, from Philadelphia, Pa., by Richlyn Laboratories, Inc.

LABEL IN PART: (Vial and ctn.) "Multiple Dose Vial Multiglands (Plurigland Extract) Intramuscular Only See Package Insert Caution * * * Distributed by Rugby Laboratories, Inc. Brooklyn, N.Y. Contains the water soluble extractives from the following dried glands: Suprarenal Cortex-Thyroid, U.S.P.-Anterior Pituitary-Posterior Pituitary-Ovarian Substance-Thymus-Lymphatic Tissue."

ACCOMPANYING LABELING: Leaflets entitled "Multiglands Extract and Multiglands Extract With D-Amphetamine Composition * * * Action and Uses: non specific protein therapy" and "Multiglands Extract Sterile-Intramuscular * * * Indications: Non-specific protein therapy."

RESULTS OF INVESTIGATION: Analysis indicated that the article contained approximately .035 milligrams of iodine per cubic centimeter. The label failed to bear adequate information for use, as required by regulations, concerning full disclosure of relevant hazards, contraindications, and side effects and precautions, since the claim of the article for nonspecific protein therapy was unreliable and was possibly harmful due to the presence of iodine.

LIBELED: 8-22-63, E. Dist. N.Y.

CHARGE: 502(f) (1)—when shipped, the labeling of the article failed to bear adequate directions for use, and it was not exempt from such requirement since its labeling failed to conform to regulations that its labeling bear adequate information for its use, including relevant hazards, contraindications, side effects, and precautions, under which licensed practitioners can use the drug safely and for all its intended purposes.

DISPOSITION: 10-8-63. Default—destruction.

7749. Lero's Monkey Brand tablets. (F.D.C. No. 49206. S. No. 4-985 X.)

QUANTITY: 1 25,000-tablet drum and 13 boxes, at Baltimore, Md., in possession of Robinson Drug Store.

SHIPPED: Between 1-5-61 and 6-25-63, from Philadelphia, Pa.

LABEL IN PART: (Drum) "Private Formula * * * Amount 52,000 * * * Sugar Coated 'Red' tablets Each containing: Pwd. Ext. Damiana 2 gr. Powd. Ext. Nux Vomica $\frac{1}{4}$ gr. (.0184 gr.) (Strychnine) Zinc Phosphide $\frac{1}{2}$ gr. Caution * * * Dose"; (box) "Lero's Monkey Brand Tablets Contents 40 Tablets Active Ingredients: Damiana, Nux Vomica, Zinc Phosphate * * * Recommended as a tonic for Physical Weakness Dose * * * Lero Drug Company, Baltimore, Maryland."

RESULTS OF INVESTIGATION: The article was shipped in bulk and some part of the article was repacked into boxes by the dealer. Examination showed that the repack boxes contained only 31 tablets. Analysis showed that the article contained the ingredients listed on the drum label.

LIBELED: On or about 8-26-63, Dist. Md.

CHARGE: 502(a)—while held for sale, the repack box label contained false and misleading representations that the article was adequate and effective as a tonic for physical weakness, and for regaining youth, strength, and vitality; 502(a)—the label (repack) stated that the article contained zinc phosphate, which statement was false, since the article contained zinc phosphide; 502(b) (1)—the repacked article was a drug in package form, and its label (repack) failed to qualify the firm as the repacker and failed to bear the street address of the firm, which was not listed in the local telephone directory; 502(b) (2)—the repacked article failed to bear a label containing an accurate statement of the quantity of the contents, since the label statement (repack) "Contents 40 Tablets" was inaccurate; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use, and adequate directions for use cannot be written for a drug containing a combination of the listed ingredients.

DISPOSITION: 10-9-63. Default—destruction.

7750. Various prescription and nonprescription drugs. (F.D.C. No. 49559. S. Nos. 34-649 X, 34-656 X.)

QUANTITY: 60 bushel baskets containing prescription drugs, such as an unlabeled btl. of sodium amytal capsules, and 125 bushel baskets containing non-prescription drugs, such as an unlabeled btl. of aspirin tablets, at Minneapolis, Minn., in possession of C. G. Urness, t/a World Salvage.

SHIPPED: Prior to 12-4-63, by unknown shippers, from outside the State of Minnesota.

RESULTS OF INVESTIGATION: Investigation showed that various foods, drugs, and cosmetics were subject to fire damage on or about 12-6-61, and that they had been held in basement storage at a retail drug store in Minneapolis, prior to receipt by the dealer. The containers were either unlabeled or bore labels damaged by fire, smoke, or water, and the cans were rusted and contaminated with dirt and debris. The drugs were not positively identifiable, some being unlabeled and some having labels attached with rubber bands.

The drugs and cosmetics were also libeled as is reported in notices of judgment on foods, No. 29500, and in notices of judgment on cosmetics, No. 252.

The articles were being held for sale by the dealer.

LIBELED: 12-9-63, Dist. Minn.

CHARGE: 501(a) (2) (A)—while held for sale, the articles had been held under insanitary conditions; 502(f) (1)—the labeling of the articles failed to bear adequate directions for use.

DISPOSITION: 12-24-63. Consent—destruction.

7751. Micro-Dynamometer devices. (F.D.C. No. 47725. S. Nos. 69-751/2 T.)

QUANTITY: 2 devices at Cambridge and Easton, Md.

SHIPPED: On unknown dates, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "Ellis Micro-Dynameter * * * Manufactured by Ellis Research Laboratories, Inc., Chicago, Ill."

RESULTS OF INVESTIGATION: Examination indicated that the devices were essentially galvanometers for measuring electrical currents and electrical potentials of small magnitude. Each device was mounted in a metal cabinet, on the face of which was a scale or meter intended to measure the flow of current in milliamperes, together with a number of dials which could be set at numbered or lettered positions. The dial settings were intended to increase or decrease the resistance to the current flowing through the device. The current which flowed and was measured by the scale or meter was generated by closing the circuit between two dissimilar metal "probes." The circuit was closed by placing the "probes" at different points on the human body, by placing the "probes" together, or by immersing them in water.

LIBELED: 7-13-62, Dist. Md.

CHARGE: 502(f) (1)—when shipped, the labeling of the articles failed to bear adequate directions for use, and they were not entitled to any exemptions from that requirement.

DISPOSITION: 8-14-62. Default—delivered to the Food and Drug Administration.

7752. Micro-Dynameter devices. (F.D.C. No. 47921. S. Nos. 62-015/6 T.)

QUANTITY: 2 devices at Lincoln and Woonsocket, R.I.

SHIPPED: Between 1-1-57 and 12-31-60, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "Manufactured by Ellis Research Laboratories, Inc., Chicago * * * The Ellis Micro-Dynameter."

ACCOMPANYING LABELING: Various pieces of literature pertaining to the device.

LIBELED: 8-15-62, Dist. R.I.

CHARGE: Device at Woonsocket, 502(a)—when shipped, the labeling of the device contained false and misleading representations that the article was adequate and effective for diagnosing disease.

Both devices, 502(f) (1)—when shipped, the labeling of the devices failed to bear adequate directions for use, and they were not entitled to any exemption from that requirement.

DISPOSITION: 8-16-62. Default—destruction.

7753. Micro-Dynameter device. (F.D.C. No. 47708. S. No. 62-246 T.)

QUANTITY: 1 device at West Dennis, Mass.

SHIPPED: On an unknown date, by an unknown shipper.

LIBELED: 7-9-62, Dist. Mass.

CHARGE: 502(f) (1)—when shipped and while held for sale, the labeling of the article failed to bear adequate directions for use.

DISPOSITION: 9-7-62. Default—delivered to the Food and Drug Administration.

7754. Micro-Dynameter devices (2 seizure actions). F.D.C. Nos. 48053, 48217. S. Nos. 86-792 T, 87-186 T.)

QUANTITY: 2 devices at Chicago, Ill.

SHIPPED: 7-21-62 and 8-27-62, from Gardena and Sacramento, Calif. These were return shipments.

LABEL IN PART: "Manufactured by Ellis Research Laboratories, Inc. Chicago * * * The Ellis Micro-Dynameter."

LIBELED: 8-17-62 and 10-5-62, N. Dist. Ill.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for diagnosing disease; and 502(f) (1)—the labeling of the articles failed to bear adequate directions for use, and they were not entitled to any exemption from that requirement.

DISPOSITION: 9-19-62, 11-2-62. Default—delivered to the Food and Drug Administration.

7755. Micro-Dynameter devices. (F.D.C. Nos. 47828, 47945. S. Nos. 61-581 T, 47-048/9 T, 61-574/6 T.)

QUANTITY: 7 devices, at Union City, Jackson, Perryville, Paris, and Memphis, Tenn.

SHIPPED: On various dates, from Chicago, Ill., By Ellis Research Laboratories, Inc.

LABEL IN PART: "For Scientific Body Analysis The Ellis Micro-Dynameter Mfd. by Ellis Research Laboratories, Inc., Chicago, U.S.A."

ACCOMPANYING LABELING: Various pieces of descriptive literature pertaining to the device.

LIBELED: 8-16-62, W. Dist. Tenn.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were of value in the diagnosis of disease; and 502(f) (1)—the labeling of the articles failed to bear adequate directions for use, and they were not entitled to any exemption from that requirement.

DISPOSITION: 9-20-62. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICES FOR HUMAN USE*

7756. Estrone injection and testosterone. (F.D.C. No. 48658. S. Nos. 26-724 V, 26-727 V.)

QUANTITY: 314 unlabeled 30-cc. vials of *estrone injection* and 39 unlabeled vials, and 13 labeled vials of *testosterone*, at Detroit, Mich., in possession of Atlas Pharmaceutical Laboratories, Inc.

SHIPPED: The articles were manufactured and packed by Atlas Pharmaceutical Laboratories, Inc., from estrone which had been shipped on 7-30-62, from Fort Lee, N.J., and from *testosterone* which had been shipped on 10-10-62, from New York, N.Y.

LABEL IN PART: (Vial) "List No. 192 Multiple Dose Vial 10 cc Size Testosterone Aqueous 100 mg. per cc * * * Intramuscular Only Atlas Pharmaceutical Laboratories, Inc. Detroit 12, Michigan."

RESULTS OF INVESTIGATION: Examination showed that the articles were contaminated with viable micro-organisms.

*See also No. 7746.

LIBELED: 3-1-63, E. Dist. Mich.

CHARGE: 501(b)—while held for sale, the articles purported to be and were represented as drugs, "Estrone Injection" and "Sterile Testosterone Suspension," the names of which are recognized in official compendiums, namely, the United States Pharmacopeia (*estrone injection*) and The National Formulary (*testosterone*), and their quality and purity fell below the standards for such drugs set forth in the compendiums.

DISPOSITION: 6-13-63. Default—destruction.

7757. Imitation Serpasil tablets, imitation Chloromycetin capsules, and imitation Diuril tablets. (F.D.C. No. 47344. S. Nos. 69-584 R, 69-595/6 R.)

INFORMATION FILED: 4-18-63, N. Dist. Ill., against Kirshenbaum Medical Supply, a partnership, Chicago, Ill., Eli Kirshenbaum, partner, and Isadore Kirschenbaum (sic), partner.

ALLEGED VIOLATION: Between 11-26-60 and 3-8-61, while quantities of *imitation Serpasil tablets*, *imitation Chloromycetin capsules*, and *imitation Diuril tablets* were being held for sale after shipment in interstate commerce, and were being represented as the authentic drugs, the defendants caused such drugs to be offered for sale and sold, which acts resulted in the drugs being adulterated.

CHARGE: 501(d)(2)—*imitation Serpasil tablets*, *imitation Chloromycetin capsules*, and *imitation Diuril tablets* had been substituted for Serpasil tablets, Chloromycetin capsules, and Diuril tablets.

PLEA: Guilty.

DISPOSITION: 6-25-63. The defendants were fined \$200, plus costs, collectively.

7758. Rubber prophylactics. (F.D.C. No. 48737. S. Nos. 28-506/7 V.)

QUANTITY: 13 ctns., each containing 72 2-unit pkgs., and 10 ctns., each containing 48 3-unit pkgs., at Kansas City, Mo.

SHIPPED: Prior to 1-25-63, from outside the State of Missouri, by an unknown shipper.

LABEL IN PART: (Pkg.) "Tops Prophylactics M & M Rubber Company, Kansas City 8 Mo. * * * See Instructions Inside," and (pkg.) "Viking Prophylactics Nipple End * * * M & M Rubber Co., K.C. 8, Mo."

ACCOMPANYING LABELING: Package insert entitled "Important Information."

RESULTS OF INVESTIGATION: The articles had been shipped to M & M Rubber Co., Kansas City, Mo., which had reshipped them to the dealer in whose possession the article had been seized.

Examination indicated between 1.8 and 1.4 percent of the articles were defective.

LIBELED: 4-5-63, W. Dist. Mo.

CHARGE: 501(c)—while held for sale, the quality of the articles differed from that which they were purported to possess; and 502(a)—the label statements (both lots) "Prophylactics" and (Vikings) "Sold for the Prevention of Disease Only" were false and misleading as applied to products containing holes.

DISPOSITION: 5-31-63. Default—destruction.

7759. Rubber prophylactics. (F.D.C. No. 49111. S. No. 38-522 X.)

QUANTITY: 86 boxes, each containing 72 2-unit pkgs., at Columbus, Miss.

SHIPPED: On or about 6-12-63. from Kansas City, Mo., by M & M Rubber Co.
LABEL IN PART: (Pkg.) "Spartans Prophylactics * * * M & M Rubber Co., K.C.
8, Mo."

RESULTS OF INVESTIGATION: Examination showed that approximately 3 percent
contained holes.

LIBELED: 7-22-63. N. Dist. Miss.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which
it was purported to possess; and 502(a)—the label statement "Sold for the
prevention of disease only" was false and misleading as applied to a product
containing holes.

DISPOSITION: 10-11-63. Default—destruction.

7760. Rubber prophylactics. (F.D.C. No. 48757. S. No. 62-744 V.)

QUANTITY: 30 ctns., each containing 72 3-unit pkgs., at Las Vegas, Nev.

SHIPPED: 3-4-63, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "VIKING PROPHYLACTICS * * * M & M RUBBER
CO. K.C., 8, MO. * * * SOLD FOR THE PREVENTION OF DISEASE
ONLY."

RESULTS OF INVESTIGATION: Examination showed that 4.5 percent of those arti-
cles examined were defective in that they contained holes.

LIBELED: On or about 5-7-63, Dist. Nev.

CHARGE: 501(c)—when shipped, the quality of the article differed from that
which it was purported to possess; and 502(a)—the label statement "SOLD
FOR THE PREVENTION OF DISEASE ONLY" was false and misleading as
applied to a product containing holes.

DISPOSITION: 7-2-63. Default—destruction.

7761. Rubber prophylactics. (F.D.C. No. 49237. S. No. 3-791 X.)

QUANTITY: 200 ctns., each containing 12 boxes, each box containing 4 3-unit
pkgs., at Baltimore, Md.

SHIPPED: 5-29-63, from Akron, Ohio, by Akwell Corp.

LABEL IN PART: (Pkg.) "The Chief Super Thin Prophylactics * * * Lee-Mor
Products Co. Baltimore 1, Md."

RESULTS OF INVESTIGATION: Examination showed that approximately 1.8 per-
cent of the article contained holes.

LIBELED: 8-26-63, Dist. Md.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which
it was purported to possess; and 502(a)—the label statements (ctn.) "Sold
for the prevention of disease only." (pkg.) "Disease Preventives," and (units)
"For Prevention of Disease," were false and misleading as applied to a product
containing holes.

DISPOSITION: 9-25-63. Default—destruction.

7762. Rubber prophylactics. (F.D.C. No. 48763. S. No. 65-313 V.)

QUANTITY: 99 gross, in pkgs. of 2 each, at Nashville, Tenn.

SHIPPED: 9-30-62, from New York, N.Y., by Allied Latex Sales Co.

LABEL IN PART: "Royal Knight Prophylactics Sold for the Prevention of Dis-
ease Only . . . Manufactured for Allied Latex Sales Co. New York 19, N.Y."

RESULTS OF INVESTIGATION: Examination showed that 2.8 percent of the prophylactics examined were defective in that they contained holes.

LIBELED: 5-3-63, M. Dist. Tenn.

CHARGE: 501(c)—when shipped, the quality of the article differed from that which it was purported to possess; and 502(a)—the label statement "Sold for the Prevention of Disease Only" was false and misleading as applied to a product containing holes.

DISPOSITION: 7-8-63. Default—destruction.

DRUGS FOR VETERINARY USE

7763. Medicated swine feed. (F.D.C. No. 48648. S. No. 46-369 V.)

QUANTITY: 28 50-lb. bags at Taylor, Mo.

SHIPPED: Between 9-28-62 and 12-11-62, from Beardstown, Ill., by the Beardstown Mills Co.

LABEL IN PART: (Tag) "Critic Super Swine Mixer Medicated * * * Active Drug Ingredient Oxytetracycline 250 grams per ton Arsanilic Acid 0.05% * * * The Beardstown Mills Company, Beardstown, Illinois."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 3 percent of the declared amount of arsanilic acid and less than 10 percent of the declared amount of oxytetracycline.

LIBELED: 2-25-63, E. Dist. Mo.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; 502(a)—the label statements "Arsanilic Acid 0.05%" and "Oxytetracycline 250 grams per ton" were false and misleading as applied to a product containing less than the declared amount of arsanilic acid and oxytetracycline; and 502(a)—the labeling of the article contained false and misleading representations that the article was adequate and effective for the prevention of swine enteritis and maintenance of weight gains in the presence of atrophic rhinitis.

DISPOSITION: 4-22-63. Default—destruction.

7764. Medicated chick feed. (F.D.C. No. 49271. S. No. 27-763 X.)

QUANTITY: 6 50-lb. bags, at Wauneta, Nebr., in possession of Wauneta Roller Mills.

SHIPPED: The nitrophenide ingredient of the article was shipped on 10-5-62, from Kansas City, Mo.

LABEL IN PART: (Tag) "Wauneta's Best Products * * * Frenchman Valley Starting Mash Medicated Feed Continuously as the Only Ration—To Aid in the Prevention of Coccidiosis—Active Drug Ingredient: Nitrophenide—0.025%—Manufactured by Wauneta Roller Mills, Wauneta, Nebraska For Baby Chick Feeding During The First Six (6) weeks."

RESULTS OF INVESTIGATION: The article was manufactured by the dealer, in part from an ingredient shipped in interstate commerce. Analysis showed that the article contained approximately 72 percent of the declared amount of nitrophenide.

LIBELED: 9-11-63, Dist. Nebr.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Nitrophenide 0.025%" was false and misleading.

DISPOSITION: 11-19-63. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS**DRUGS AND DEVICES FOR HUMAN USE***

7765. Nitroglyn tablets. (F.D.C. No. 47582. S. Nos. 63-921/2 T.)

QUANTITY: 9,993 50-tablet btls. and 497 12-tablet pkgs., of 1/25-gr. tablets, and 3,449 50-tablet btls. and 497 12-tablet pkgs., of 1/10-gr. tablets, at Miami, Fla., in possession of Key Pharmaceuticals, Inc.

SHIPPED: 12-28-61 and 2-24-62, from Brooklyn, N.Y.

LABEL IN PART: (Btl.) "50 Tablets Nitroglyn Nitroglycerin Each Sustained Action Tablet Provides: Nitroglycerin 1/25 gr. (2.6 mg.) [or "1/10 gr. (6.4 mg.)"] Caution: * * * Manufactured for Key Pharmaceuticals, Inc., Miami 37, Florida Indications: * * * Contraindications."

ACCOMPANYING LABELING: Package insert and physician's index card entitled "Nitroglyn tablets," and brochures entitled "Prevent Angina Attacks with Nitroglyn" and "Something Old—Nitroglycerin—Something New—Nitroglyn."

RESULTS OF INVESTIGATION: The articles had been repacked by the dealer from bulk stock which had been shipped as above. The accompanying labeling was used in promoting sales of the article.

Analysis showed that the 1/25-gr. tablets released, on the average, approximately 58 percent of the nitroglycerin in 1 hour and approximately 80 percent of the nitroglycerin within 2 hours; and the 1/10-gr. tablets released, on the average, approximately 53 percent of the nitroglycerin within 1 hour and approximately 75 percent of the nitroglycerin within 2 hours.

LIBELED: 5-8-62, S. Dist. Fla.; libel amended 9-25-63.

CHARGE: 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the active ingredient of the articles, namely, nitroglycerin, was released upon ingestion at a uniform rate over a period of 8 to 12 hours.

DISPOSITION: On 6-19-62, Bonded Laboratories, Inc., claimed the articles. On 7-26-62, upon consent of the parties, the action was removed to the United States District Court for the District of New Jersey. On 9-25-63, the libel was amended to allege that the articles released approximately 76 percent of the nitroglycerin ingredient in 4 hours time. On 10-23-63, the claimant having withdrawn its claim and answer, a decree of condemnation and destruction was entered.

7766. Camatuss. (F.D.C. No. 48176. S. No. 75-025 R.)

INFORMATION FILED: 8-13-63, W. Dist. S.C., against Cambridge Pharmaceuticals, Inc., Greenville, S.C., and Perry L. Boggs, president.

SHIPPED: Between 5-10-61 and 6-7-61, from South Carolina to North Carolina.

LABEL IN PART: "CAMATUSS: Vasoconstrictor, Antihistamine with Codeine Each 5 ml (one teaspoonful) represents: Codeine Sulfate 10.0 mg Cambridge Pharmaceuticals, Inc. Greenville, South Carolina."

CHARGE: 502(a)—when shipped, the label statement of the quantity of codeine sulfate present in the drug was false and misleading.

PLEA: Guilty.

DISPOSITION: 10-28-63. Each defendant—\$500 fine.

*See also Nos. 7746, 7749, 7752, 7754, 7755, 7758-7762.

7767. Dexaphene tablets. (F.D.C. No. 49119. S. No. 2-709 X.)

QUANTITY: 117 60 tablet vials, at Atlanta, Ga., in possession of Best Drug Co.

SHIPPED: 6-19-63, from Cleveland, Ohio, by Reese Chemical Co.

LABEL IN PART: "Dexaphene Tablets To Help You Lose Weight * * * 60 Tablets Each contain: Phenyl Propanolamine Hydrochloride 25 mg. Thiamine Mononitrate 5 mg. Riboflavin 2 mg. Niacinamide 3.4 mg. Ascorbic Acid 10 mg. Dextrose 2 gr. Sodium Caseinate 1 gr. The new approach to Reducing Distributed by Best Cut Rate Drugs * * * Atlanta, Ga."

ACCOMPANYING LABELING: Display placard reading in part "Lose Weight Look Better Live Longer * * * Control Your Appetite"; 2 newspaper tear sheets reading in part "Eat Less-Live Longer Sensational New Appetite Depressant Tablets * * * Dexaphene"; and leaflets reading in part "Eat Less—Live Longer Sensational new Appetite Depressant Tablets."

RESULTS OF INVESTIGATION: The placards and leaflets had been shipped to the dealer by the shipper; the newspaper tear sheets had been prepared by the dealer.

LIBELED: 7-19-63, N. Dist. Ga.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective for overcoming obesity through appetite control; for removing excess body weight and depressing the appetite, resulting in less food intake, loss of weight, and longer life.

DISPOSITION: 8-27-63. Default—destruction.

7768. Bio-Miracle cream. (F.D.C. No. 45333. S. No. 42-752 R.)

QUANTITY: 43 1-oz. jars, 17 2-oz. jars, and 5 4-oz. jars, at San Francisco, Calif.

SHIPPED: 9-16-60 and 10-25-60, from New York, N.Y., by Germaine Monteil Cosmetiques Corp.

LABEL IN PART: "Bio-Miracle Cream Germaine Monteil * * * Directions * * * Contains 110 milligrams of Biotene per ounce of cream * * * Germaine Monteil New York."

ACCOMPANYING LABELING: Leaflets entitled "Germaine Monteil Bio-Miracle Cream"; folders entitled "Bio-Miracle Cream"; pamphlets entitled "Simple Steps to Beauty"; and counter display placards entitled "Miracles Don't just happen; they are caused."

LIBELED: 1-12-61, N. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article, (1) was the world's first "specific" against lines, (2) contained regenerative substances, (3) worked below the surface to regenerate cellular activity, and (4) reestablished the skin's urge to nourish itself; and 502(e) (2)—the label of the article failed to bear the common or usual name of each active drug ingredient therein.

DISPOSITION: The article was claimed by Germaine Monteil Cosmetiques Corp., and on 3-8-61, the case was removed to the District of New Jersey. On or about 3-29-62, the Government filed written interrogatories. On 8-29-63, a consent decree of condemnation was entered and the article was released under bond for relabeling.

7769. Lovelite acne lotions. (F.D.C. No. 49300. S. Nos. 49-450/1 X.)

QUANTITY: 144 4-oz. btls. of acne lotion for teenage girls, and 86 4-oz. btls. of acne lotion for young men, at Bakersfield, Calif.

SHIPPED: 1-17-63 and 3-15-63, from Las Vegas, Nev., by Lovelite Cosmetics, Inc.

LABEL IN PART: (Btl.) "Lovelite Acne Lotion Created Especially For Teenage Girls Skin Problems Clinically Proven—Lovelite Cosmetics, Inc. Las Vegas, Nevada"; (btl.) "Lovelite Formula LV-16 Acne Lotion Researched and Formulated For Young Men—Lovelite Cosmetics, Inc. Las Vegas, Nevada."

RESULTS OF INVESTIGATION: Examination showed that the articles consisted of a gelatinous semisolid substance.

LIBELED: 9-10-63, S. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling of both articles contained false and misleading representations that the articles were adequate and effective as a treatment for acne.

DISPOSITION: 10-7-63. Default—destruction.

7770. Lan-Lay lotions. (F.D.C. No. 49113. S. Nos. 66-891/2 V.)

QUANTITY: 576 4-oz. btls. of *Lan-Lay for skin dryness*, and 72 12¼-oz. btls. of *Lan-Lay for skin, hair, and scalp dryness*, at Atlanta, Ga.

SHIPPED: 5-17-63, from San Francisco, Calif., by Lan-Lay, Inc.

LABEL IN PART: "Lan-Lay Contains Wool Fat (Lanolin) The Modern Many Use Cosmetic for Skin Dryness * * * Lan-Lay, Inc. 55-11th Street, San Francisco, Calif.," and "Lan-Lay Does It * * * Contains Wool Fat (Lanolin) The Modern Many Use Cosmetic For Skin Hair and Scalp Dryness * * * Lan-Lay Inc. 55-11th Street, San Francisco 3, Calif."

ACCOMPANYING LABELING: Comic books entitled "The Royal Chef The Fanciful story of Lan-Lay."

RESULTS OF INVESTIGATION: Information obtained during an inspection of Lan-Lay, Inc., manufacturer, indicated that the product contained 8 percent lanolin and 92 percent mineral oil.

LIBELED: 7-16-63, N. Dist. Ga.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were an adequate and effective treatment for all chronic dry-skin conditions; for lubricating scar tissue; as a dressing in X-ray therapy; as a lubricant for probing instruments; for retarding the aging processes of the skin; for clogged pores, blackheads, and blemishes; as a healing aid to skin grafting; to prevent striations during pregnancy; and that the articles were 100 percent pure.

DISPOSITION: 8-19-63. Default—destruction.

7771. SDA food supplement capsules. (F.D.C. No. 48268. S. No. 5-218 T.)

QUANTITY: 7 ctns., each containing 28 boxes, containing 42 2-capsule envelopes each; and 1 ctn. containing 16 boxes, containing 42 2-capsule envelopes, at Baltimore, Md., in possession of Nutrodynamics, Inc.

SHIPPED: 5-24-62 and 5-25-62, from Newark, N.J., by Ivers-Lee Co.

LABEL IN PART: (Envelope) "SDA Food Supplement for dietary type of reduction * * * Nutrodynamics, Inc. * * * Miami 37, Florida * * * a low caloric food supplement."

ACCOMPANYING LABELING: Leaflet entitled "SDA's contribution to your weight reduction program."

RESULTS OF INVESTIGATION: The leaflet had been printed on order of the dealer and had been enclosed in each box of the article by the shipper.

LIBELED: 11-6-62, Dist. Md. —

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective for weight reduction while maintaining the protein content at normal levels; to maintain energy, vitality, strength and health; control the appetite; increase life expectancy; prevent deficiencies in all nutrients essential to adequate nutrition even during the most vigorous dietary restrictions; and that the article was of unusually significant value for special dietary supplementation and therapeutic use by reason of the presence therein of protein in an amount which was low in calories.

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 4-10-63. Default—destruction.

7772. Oxygen inhalator. (F.D.C. No. 48074. S. Nos. 17-876/7 T.)

QUANTITY: 2 devices in metal cases, and 5 devices in alligator-covered cases, and attachments, at Indianapolis, Ind.

SHIPPED: 12-15-61 and 1-28-62, from Chicago, Ill., by Oxy-Gear, Inc.

LABEL IN PART: (Metal case lid) "Oxygen Inhalator Emergency Oxygen Mfg. by Oxy-Gear, Inc., Chicago, Ill."; (inside lid of metal and alligator cases) "Oxy-Gear Inhalator Technique For Use * * * Mfd. by Oxy-Gear, Inc. * * * Chicago 2, Illinois."

ACCOMPANYING LABELING: Leaflets entitled "The Most Wanted Oxygen Inhalator Kit in Years," "Deluxe Oxygen Inhalator Kit Alligator Case," and "Important Instructions"; pamphlets entitled "Don't Stay Awake To Die"; and letter dated 6-29-62, on Oxy-Gear, Inc., letterhead, addressed to "Dear Dick" and signed "Sincerely yours, Ed."

LIBELED: 9-19-62, S. Dist. Ind.

CHARGE: 502(a)—when shipped, the accompanying labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for relieving sudden cardiac and asthmatic attacks, shortness of breath, and lung conditions; and for overcoming effects of shock, smoke inhalation, migraine headaches, exhaustion, hangover, and driving fatigue.

DISPOSITION: 12-28-62. Consent—claimed by Oxy-Gear, Inc., and relabeled.

7773. Rilecoe Therapeutic Filter Lamp. (F.D.C. No. 49325. S. No. 20-523 X.)

QUANTITY: 2 devices at Oklahoma City, Okla.

SHIPPED: 6-18-62, from Pinehurst, N.C., by Rile-Coe Filter Process, Inc.

LABEL IN PART: "Rilecoe Therapeutic Filter Lamp."

ACCOMPANYING LABELING: Memo re Rile Coe Therapeutic Filter Lamp signed E. G. B. Riley, Pinehurst, North Carolina; letters signed E. G. B. Riley dated 10-13-61, 6-22-62, and 9-20-62; case reports of Dr. Francis L. Owens, M.D., dated April, 1952; undated memorandum from E. G. B. Riley; and undated memorandum of case reports.

RESULTS OF INVESTIGATION: Examination indicated that the device consisted of a filter lamp with portable stand, cord, switch, reflector, lenses, filters, and accessories.

LIBELED: 9-20-63, W. Dist. Okla.

CHARGE: 502(a)—when shipped, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the treatment of burns, eliminating blood and plasma transfusions, arresting and overcoming malignancies, and treatment of nuclear bomb burns.

DISPOSITION: 10-28-63. Default—delivered to the Food and Drug Administration.

7774. Safe-T-Sun Lamp. (F.D.C. No. 47547. S. No. 5-532 T.)

QUANTITY: Unassembled parts for 29 devices, individually ctnd. in two ctns. each, at Williamsburg, Va.

SHIPPED: Prior to 2-15-62, from Bridgeport, Pa., by Safe-T-Sun Corp., to Worcester, Mass., from where it was reshipped by Denholm & McKay Co., on 2-15-62, to Williamsburg, Va.

LABEL IN PART: (Ctn. containing base standard filters in envelopes, and literature) "Part 1 45 3401 Safe-T-Sun Corp. Williamsburg, Va."; (ctn. containing lamp) "Part 2 46 3401 Glass Sun Lamp Safe-T-Sun Corp. Williamsburg, Va."; (filter envelope) "Assembly of Health Tan Sun Lamp * * * Operating Instructions"; (folder in ctn.) "Yes! This is the amazing new Safe-T-Sun Health-Tan Sun Lamp That Can't Burn * * * the only truly safe sun lamp with built-in health benefits Catalina Model."

ACCOMPANYING LABELING: Folders entitled "the amazing new Safe-T-Sun Health Lamp sun lamp Can't Burn"; and leaflets entitled "Sell New Safe-T-Sun Health-Tan Sun Lamp."

RESULTS OF INVESTIGATION: Examination indicated that the article was a commercially available Sylvania ultraviolet lamp fitted with a polyester film filter and adjustable reflector. The unit was then fitted to a floor stand.

LIBELED: On or about 4-20-62, E. Dist. Va.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for relieving tired back, stiff neck, arthritic-like pains, skin problems, and aching muscles, toning the skin, and overcoming adolescent skin problems; that the filter would permit unlimited use of the lamp to provide a tanning effect without painful burning; and that the article could be used as a "sun lamp that can't burn."

DISPOSITION: 4-10-63. Default—destruction.

7775. Safe-T-Sun Health-Tan Sun Lamps. (F.D.C. No. 48981. S. No. 69-102 V.)

QUANTITY: 96 deluxe models and 5 professional models, at Salem, Va.

SHIPPED: 4-8-63 and 5-3-63, from New York, N.Y., by Celebrity Merchandisers, Inc.

LABEL IN PART: (Lamp bulb) "Safe-T-Sun Health-Tan Sun Lamp," and (filter) "Can't Burn Health-Tan Sun Lamp Filter * * * Jayne Mansfield Richmond, Va."

ACCOMPANYING LABELING: Leaflets entitled "Jayne Mansfield 'Can't Burn' Health-Tan Patented Sun Lamp" and "Operating Instructions for the Jayne Mansfield Health-Tan Sunlamp"; and brochures entitled "Jayne Mansfield Patented Health-Tan Sunlamp with exclusive 'Can't Burn' Feature"; and

pamphlets, counter displays, and floor displays entitled "New! Jayne Mansfield Patented Health-Tan Sun Lamp—The only Sunlamp that Can't Burn."

RESULTS OF INVESTIGATION: The article was an electrical lamp fixture containing a 275-watt ultraviolet lamp and holder for the Mylar and/or acetate filters. The lamp was supported on a tripod for floor or table use or by a clamp unit.

LIBELED: 6-18-63, W. Dist. Va.; amended libel 6-25-63.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was adequate and effective as a treatment for relieving tired back, stiff neck, arthritic-like pains, skin problems, and aching muscles, and toning the skin; that the filter would permit unlimited use of the lamp to provide a tanning effect without painful burning; and that the article could be used as a "sun lamp that can't burn."

DISPOSITION: 9-9-63. Consent—claimed by M & M Distributors, Inc., Salem, Va., and released under bond for relabeling.

7776. Leg rejuvenator device. (F.D.C. No. 48816. S. No. 8-405 V.)

QUANTITY: 8 devices in labeled ctns. and 22 unlabeled ctns. of 1 device each, at Boston, Mass., in possession of Jos. Breck & Sons Corp.

SHIPPED: Between 9-14-62 and 3-11-63, from Yonkers and New York, N.Y., by Beacon Enterprises, Inc.

LABEL IN PART: (Ctn.) "Style #455 Leg Rejuvenator by Beacon Give a lift to your legs and heart * * * Beacon Enterprises, Inc. * * * N.Y., N.Y."

ACCOMPANYING LABELING: Instruction sheet and leaflets entitled "Style #455 Leg-Rejuvenator by Beacon" and "Electric-Vibro Leg Rejuvenator"; and sales catalog entitled "Sale 146th Anniversary, Breck's of Boston."

RESULTS OF INVESTIGATION: The devices appeared to be fabric-covered tubular metal frames with or without an electric vibrator attached.

LIBELED: 3-20-63, Dist. Mass.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the article was adequate and effective for improving blood circulation, easing heart strain, and reducing leg swelling.

DISPOSITION: 8-5-63. Default—ordered destroyed or delivered to a charitable institution for its use, with a warning that the article had no therapeutic value.

7777. Aqua-Laxer Hydro-Massage units. (F.D.C. No. 48280. S. No. 19-743 V.)

QUANTITY: 7 individually ctnd. devices, at Houston, Tex., in possession of Aqua-Laxer Distributing Co.

SHIPPED: Between 5-11-62 and 7-1-62, from Seattle, Wash., and Santa Clara, Calif.

LABEL IN PART: (Ctn.) "Contains Aqua-Laxer Hydro-Massage Unit * * * Manufactured by Aqua-Laxer Manufacturing Corp. Seattle 3, Wash.," and (device) "Aqua-Laxer Mfg. By Aqua-Laxer Mfg. Corp. 315 N. 36th St., Seattle 3, Wn."

ACCOMPANYING LABELING: Brochures and display signs entitled "You Are As Young As You Feel."

RESULTS OF INVESTIGATION: Photographs and the literature indicated that the article was a perforated plastic mat, a flexible hose, and a motor-driven air blower. The device produced a flow of air bubbles in bath water.

LIBELED: 11-14-62, S. Dist. Tex.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for poor circulation, muscle fatigue, arthritis, rheumatism, bursitis, neuritis, mental and physical tension, varicose veins, backache, nervous conditions, and sinus congestion; and that the use of the article would improve health and vitality, prevent discomforts, tranquilize, cleanse the muscle tissues, make one feel younger, and was like a fountain of youth.

DISPOSITION: 5-8-63. Consent—claimed by Aqua-Laxer Distributor of Texas, Inc., Houston, Tex., and relabeled.

7778. Veltron chin massagers and roller massagers. (F.D.C. No. 49234. S. Nos. 41-077/8 X.)

QUANTITY: 6 *chin massagers* and 7 *roller massagers*, at New York, N.Y.

SHIPPED: 4-22-63, from Anaheim, Calif., by S. L. McNair Corp.

LABEL IN PART: (Pkg.) "Veltron Electric Chin Massager * * * A Product of the S. L. McNair Corporation, Anaheim, California"; (device paper label) "Electronic Veltron Massager Model No. * * * A Product of S. L. McNair Corp. Anaheim, Calif."; (pkg.) "Veltron Roller Massager . . . for feet and body! * * * Model * * * The S. L. McNair Corporation Anaheim, California"; (plate on roller) "Veltron * * * A Product of The L. McNair Corporation, Anaheim, Calif."; and (plastic basin) "Veltron Hydrotherapy Foot and Body Massager."

ACCOMPANYING LABELING: Package inserts entitled "Veltron Electronic Under Chin Massager" and "Another guaranteed Veltron Product * * * The S. L. McNair Corporation * * * Anaheim, Calif."

RESULTS OF INVESTIGATION: Examination showed that the *chin massager* consisted of a 110-120-volt AC motor in a plastic housing. The vibrator surface was curved to fit the underchin. A head strap accompanied the vibrator (for attachment to the head) and a plug-in cord 6 feet long.

Examination showed that the *roller massager* consisted of a 110-120-volt AC motor in a plastic housing and that the vibrator surface was cylindrical in shape with a plug-in cord 6 feet long.

LIBELED: On or about 8-27-63, S. Dist. N.Y.

CHARGE: *Chin massager*, 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective to firm up sagging, flabby, underchin and throat muscles and throat wrinkles; and *roller massager*, 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective to relieve tension, stimulate and increase circulation, that the benefits derived were equal to those obtained through a Swedish massage, and eased aches and pains.

DISPOSITION: 10-1-63. Default—destruction.

7779. Contour chair. (F.D.C. No. 48812. Inj. No. 463. S. No. 71 V.)

QUANTITY: 12 devices, at Tampa, Fla., in possession of Contour Chair Shop.

SHIPPED: Between 11-9-62 and 2-13-63, from St. Louis, Mo.

ACCOMPANYING LABELING: Placards entitled "Contour * * * Relief From Nervous Tension-Fatigue-Exhaustion-Asthma-Hay Fever," and "Relief From Arthritis-Rheumatism-Heart-Circulatory Cond.-Edema-Varicose Veins."

RESULTS OF INVESTIGATION: Examination indicated that the article was an upholstered, contoured, reclined chair with a built-in heating pad and vibrator. The accompanying labeling had been prepared by the dealer for the purpose of promoting sales of the article.

LIBELED: 3-18-63, M. Dist. Fla.

CHARGE: 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective as a treatment for heart and circulatory conditions, edema, varicose veins, arthritis, rheumatism, asthma, and hay fever.

DISPOSITION: 4-10-63. Consent—claimed by Eugene & Rossi J. Grady, t/a Contour Chair Shop, and relabeled. The consent decree of condemnation also permanently enjoined the claimant from shipping in interstate commerce, any "Contour" chair which was represented as an adequate and effective treatment for heart and circulatory conditions, edema, varicose veins, arthritis, rheumatism, asthma, and hay fever; and the decree further permanently enjoined the claimant from doing or causing to be done any act with respect to any "Contour" chair, while it was held for sale after shipment in interstate commerce, which would result directly or indirectly in it being represented as an adequate and effective treatment for heart and circulatory conditions, edema, varicose veins, arthritis, rheumatism, asthma, and hay fever.

DRUG FOR VETERINARY USE*

7780. Edd's Stock Conditioner. (F.D.C. No. 49127. S. Nos. 27-463/4 X.)

QUANTITY: 7 25-lb. drums at Milford, Nebr., and 9 25-lb. drums at Beemer, Nebr.

SHIPPED: 8-4-62 and 8-17-62, from Defiance, Ohio, by Floyd Edds.

LABEL IN PART: (Drum) "Edds Stock Conditioner A Tonic For All Poultry, Hogs and Cattle Directions * * * Statement of Ingredients Sulphur-White Middlings-Linseed Meal-Bi-Carbonate Soda-Jamaica Ginger-Blood Root-Capsicum * * * Prepared and Sold by Floyd Edds, Rt. 8, Defiance, Ohio."

ACCOMPANYING LABELING: Leaflets entitled "Edd's Poultry & Hog Tonic For Chickens, Turkeys and Hogs Prepared and Sold by Floyd Edds Route 8 Defiance, Ohio," and "Edds Stock Conditioner * * * Prepared and Sold by Floyd Edds, Rt. 8, Defiance, Ohio."

LIBELED: 7-23-63, Dist. Nebr.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for the prevention of colds, blue comb, blackhead, and coccidiosis in chickens and turkeys, and maintaining egg production in poultry.

DISPOSITION: 10-14-63. Default—destruction.

*See also Nos. 7763, 7764.

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¹(7779) Injunction issued.

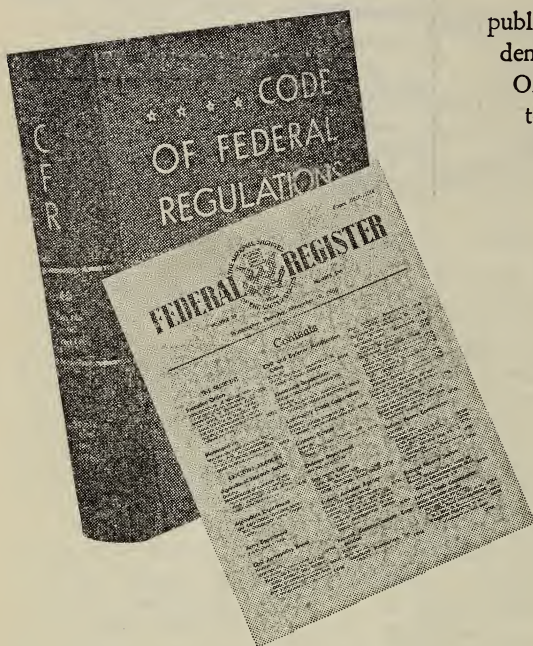
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¹(7779) Injunction issued.

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32Nd

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD,
DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug and Cosmetic Act]

7781-7840

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were alleged to be adulterated or misbranded, or otherwise violative of the Act, when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent, or, in one case, judgment by the court; (2) criminal proceedings which were terminated upon pleas of guilty and nolo contendere; and (3) injunction proceedings in which decrees of permanent injunction were entered by consent. The seizure proceedings are civil actions taken against the goods alleged to be in violation, and the criminal and injunction proceedings are against the firms or individuals charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., November 23, 1964.

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SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN ALLEGED VIOLATIONS REPORTED IN D.D.N.J. NOS. 7781-7840

Adulteration, Section 501(a) (4) (B), the article was a color additive, the intended use of which, in or on drugs, was for the purposes of coloring only and was unsafe within the meaning of Section 706(a); Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from and its quality fell below, the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from or its purity or quality fell below, that which it purported or was represented to possess; Section 501(d) (2), the article was a drug, and a substance had been substituted therefor; and Section 706(a), a color additive was deemed to be unsafe because there was not in effect a regulation listing such additive for a particular use.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(c), a word, statement, or other information required by, or under authority of, the Act to appear on the label or labeling of the article was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(d), the article was for use by man, and it contained a quantity of a chemical derivative of barbituric acid, which derivative had been found to be, and by regulation designated as, habit forming, and its label failed to bear the name, and quantity or proportion of such derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming"; Section 502(e), the label of the article failed to bear the established (common or usual) name of the drug, and of each active ingredient including the quantity, kind, and proportion of alcohol; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i) (2), the article was an imitation of another drug; Section 502(i) (3), the article was offered for sale under the name of another drug; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; Section 502(l), the article was composed wholly or in part of a kind of penicillin, streptomycin, chlortetracycline, bacitracin, or some derivative thereof, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; Section 502(m), the article was a color additive, the intended use of which, in or on drugs, was for the purpose of coloring only, and its packaging and labeling were not in conformity with packaging and labeling requirements applicable to the color additive contained in the regulations; and Section 503(b) (4), the article was a drug subject to Section 503(b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription," or the article was a drug to which Section 503(b) (1) did not apply, and its label bore the preceding quoted caution statement.

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application, or an approval of an application, filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

DRUGS FOR HUMAN USE

7781. Bio-Atric tablets and Bio-Atric elixir. (F.D.C. No. 48232. S. Nos. 88-309/11 T.)

QUANTITY: 1 3,000-tablet bulk drum, 3 labeled 500-tablet btl., and 8 unlabeled 500-tablet btl., of *Bio-Atric tablets*; 9 labeled 1-pt. btl., 1 ctn. of 6 labeled 16-oz. btl., and 3 ctns. of 6 unlabeled 16-oz. btl., of *Bio-Atric elixir*; and 1 20,400-tablet bulk drum and 1 10,050-tablet bulk drum of *Bio-Atric tablets of Lot No. 314*.

SHIPPED: Between 6-15-56 and 5-31-60, the *Bio-Atric tablets of Lot No. 314*, from Greer, S.C., by Libby, Edwards & Brown, Inc., and the other articles from Kalamazoo, Mich., and Greenville, S.C.

LABELS IN PART: (Btl.) "Bio-Atric Vitamins-Hormones-Minerals Lipotropic Factors Pediatric-Climacteric-Geriatric * * * Each tablet contains: Methyl Testosterone 2.5 mg. Ethinyl Estradiol .005 mg. Methamphetamine 1 mg. * * * Professional literature on request * * * Distributed by Bio-Factor Laboratories, Marshville, N.C."; (btl.) "Bio-Atric Elixir Vitamins-Hormones-Minerals Lipotropic Factors Pediatric-Climacteric-Geriatric * * * Each Fluid Ounce Contains: Methyl Testosterone 5 mg. Ethinyl Estradiol .01 mg. Methamphetamine 2 mg. * * * Literature available to physicians on request. Distributed by Bio-Factor Laboratories Marshville, N.C."; (drum) "Bio-Atric Lot: 314 Vitamin-Hormones-Minerals Lipotropic Factors Pediatric-Geriatric Each tablet contains: Methyl Testosterone 2.5 mg. Ethinyl Estradiol .005 mg. Methamphetamine 1 mg. * * * Libby Edwards Brown, Inc. * * * Memphis, Tennessee."

RESULTS OF INVESTIGATION: The *Bio-Atric tablets* had been shipped in bulk drums and were intended to be repacked by the dealer; the *Bio-Atric tablets* in bottles had been repacked by the dealer from bulk stock; and the *Bio-Atric elixir* had been shipped in unlabeled pint bottles which the dealer had, in part, labeled as above.

Analysis showed that the *Bio-Atric tablets of Lot No. 314* contained approximately 40 percent of the declared amount of vitamin D and thiamine hydrochloride; that the other *Bio-Atric tablets* contained approximately 60 percent of the declared amount of thiamine and 74 percent of the declared amount of folic acid; and that the *Bio-Atric elixir* contained approximately 60 percent of the declared amount of thiamine hydrochloride and 81 percent of the declared amount of riboflavin.

LIBELED: 10-12-62, W. Dist. N.C.

CHARGE: 501(c)—while held for sale, the strength of all the articles differed from that which they were purported to possess; 502(a)—the *Bio-Atric tablets of Lot No. 314*, when shipped, and the other articles, while held for sale, were misbranded in that their labeling, namely, the drum and bottle labels, contained false and misleading representations that the articles were adequate and

effective for the treatment of metabolic failure associated with pediatric, climacteric, and geriatric growth, or sex-linked or stress-linked diseases occurring at any age of life; 502(f) (1)—the *Bio-Atric tablets of Lot No. 314*, when shipped, and the other articles, while held for sale, were misbranded in that their labeling (bulk and repack) failed to bear adequate directions for use, since the labeling failed to bear adequate information regarding the effects, dosages, frequency, duration of administration, and all relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the drugs could use the drugs safely and for all the purposes for which they were intended, as required by regulations; and 502(j)—the *Bio-Atric tablets of the Lot No. 314*, when shipped, and the other articles, while held for sale, were misbranded in that they were dangerous to health when used for pediatric purposes as recommended in their labeling.

DISPOSITION: 12-6-63. Default—destruction.

DRUGS FOR VETERINARY USE

7782. Medicated feeds. (Inj. No. 416.)

COMPLAINT FOR INJUNCTION FILED: 9-13-61, N. Dist. N.Y., against Elmore Milling Co., Inc., Oneonta, N.Y.

CHARGE: The complaint alleged that the defendant was engaged in the business of manufacturing, preparing, packing, selling, and shipping in interstate commerce, articles of drug which were adulterated and misbranded, and that the defendant was doing certain acts which resulted in the adulteration and misbranding of articles of drug which were held for sale by the defendant after shipment in interstate commerce.

The complaint alleged that various of the articles of drug, when shipped and while held for sale, were adulterated and misbranded in the following respects: (i) 501(c)—their strength differed from, and their quality fell below, that which they purported and were represented to possess; (ii) 502(a)—the labeling of a number of the articles contained false and misleading statements with respect to the nature and quantity of the ingredients contained in the articles; (iii) 502(b) (2)—their labels failed to contain an accurate statement of the quantity of the contents in terms of weight and measure; (iv) 502(j)—they were dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in their labeling; (v) 502(l)—they were composed in part of penicillin or bacitracin and were not from batches with respect to which certificates or releases had been issued pursuant to 507 and they were not exempt from the requirement of such certification.

The complaint alleged further that the adulterated and misbranded conditions of the articles of drug resulted from deficiencies in the ingredients of the articles, or the presence in the articles of ingredients in excess of the amounts declared or represented to be present, which were due to inadequate manufacturing facilities, lack of ingredient and product identification, lack of production controls, lack of adequate analyses and formulas, or lack of other precautions essential to the manufacture and preparation of such drugs; for example, the *Elmore Chixsaver (1S)* was declared to contain .005% of 3-Nitro-4-hydroxyphenylarsonic acid, but contained only .0031% of that drug was declared to contain .015% of sulfaquinoxaline, but contained .022%, .0256%, .0400%, and .0435% of that drug (in different batches), and was declared to contain .01% of arsanilic acid, but contained .0263% and .0292%

of that drug (in different batches); the *Elmore Chixsaver* (1N) was declared to contain .005% of 3-Nitro-4-hydroxyphenylarsonic acid, but contained .0084% of that drug, and was declared to contain .0125% of nicarbazin, but contained only .0088% of that drug; the *Elmore Chixsaver (Medicated Feed)* was from 34% to 68% deficient in the declared amount of 3-Nitro-4-hydroxyphenylarsonic acid; the *Elmore Egg Mash* (1A) was declared to contain .005% of 3-Nitro-4-hydroxyphenylarsonic acid, but contained only .0014% of that drug; the *Elmore Complete Market Egg Mash (Ration)* (1A) was declared to contain .005% of 3-Nitro-4-hydroxyphenylarsonic acid, but contained only .0015% of that drug; the *Elmore Complete Market Egg Ration* was declared to contain .005% of 3-Nitro-4-hydroxyphenylarsonic acid, and on one occasion contained none of that drug, and was declared to contain .01% of arsanilic acid, but contained only .0068% of that drug; the *Elmore Turkey Growing Mash* (1A) was declared to contain 20% protein, but contained only 17.8% of that ingredient, and was declared to contain .005% of 3-Nitro-4-hydroxyphenylarsonic acid, but contained .0028% of that drug in one batch and .0065% in another; the *Turkey Growing Mash* (1H) was declared to contain 20% protein, but contained only 16% of that ingredient, and was declared to contain .025% of 4-nitrophenylarsonic acid, but contained only .0126% of that drug; the *Elmore Turkey Finisher* had no declaration of 3-Nitro-4-hydroxyphenylarsonic acid, but was found to contain .0032% of that drug; and *Elmore poultry feeds*, on different occasions and as the result of separate analyses, have been found to have the following variances: Arsanilic acid, declared to be .01% on the label, was not present; nicarbazin was present in only 50% of the declared amount; sulfaquinoxaline, declared to be .0175% on the label, was found to be from 50% deficient to 70% excessive in the actual content; 4-nitrophenylarsonic acid, declared to be .025% of the contents on the label, was found in the product in the following amounts: .013%, .017%, .018%, .047%, .058%, .066%, .073%, .081%, .088%, .089% and .091%.

The complaint also alleged adulterations and misbrandings with respect to feeds shipped and held for sale by the defendant, as reported in notices of judgment on foods.

The complaint alleged further that the defendant was well aware that its activities were violative of the Federal Food, Drug, and Cosmetic Act; that inspections of the defendant's plant at Oneonta, N.Y., were made by inspectors of the Federal Food and Drug Administration on 3-31-59, 11-4-59, and 8-9-61; that, on each occasion, the defendant was informed of inadequacies in its control system for the manufacture of its medicated feeds; that the defendant had been warned further by seizures of shipments of its medicated feeds in April 1960 and in August 1961, by hearings pursuant to Section 305 of the Act, by the filing of a criminal prosecution against this defendant and its vice president, treasurer, and manager on 8-15-61, and by suspension of exemptions granted to the defendant, pursuant to Sections 502(1) and 507(c) of the Act and regulations issued thereunder, authorizing the defendant to manufacture certain feeds containing antibiotics and drugs; that, in addition, during the years 1959, 1960, and 1961, more than twenty reports of improper and violative samples of the defendant's medicated feeds were made by regulatory agencies in the States of Massachusetts, New York, and Connecticut; that, despite the warnings conveyed to the defendant by the aforesaid establishment inspections, seizures, hearings, reports of violation, and criminal prosecution, the defendant continued to introduce and cause to be introduced, and deliver and cause to be delivered for introduction into interstate commerce, articles of food and

drug which were adulterated and misbranded and, despite such warnings, the defendant continued to do certain acts, while articles of food and drug were held for sale after shipment in interstate commerce, which resulted in articles of food and drug being adulterated and misbranded.

DISPOSITION: On 12-7-61, a consent decree of permanent injunction was filed pursuant to which the defendant was perpetually restrained and enjoined as follows:

1. From directly or indirectly introducing or causing to be introduced, and delivering or causing to be delivered for introduction into interstate commerce, in violation of the law, any articles of food or drug or any of its feed products which were adulterated or misbranded within the meaning of 402(a) (1), 402(a) (2), 403(a), 403(e) (2), 501(c), 502(a), 502(b), 502(j) or 502(l), because of deficiency or excess in the amounts of declared ingredients, inadequate manufacturing facilities, lack of adequate identification and production controls, lack of adequate analyses and formulas, or lack of other precautions essential to the manufacture and preparation of such articles or products;

2. From directly or indirectly causing any acts to be done, in violation of the law, with respect to any articles of food or drug while such articles were held for sale after shipment in interstate commerce, which act resulted in any such article being misbranded or adulterated within the meaning of 402(a) (1), 402(a) (2), 403(a), 403(e) (2), 501(c), 502(a), 502(b), 502(j), or 502(l), because of deficiency or excess in the amounts of declared ingredients, inadequate manufacturing facilities, lack of adequate identification and production controls, lack of adequate analyses and formulas, or lack of other precautions essential to the manufacture and preparation of such articles;

3. From preparing, shipping, selling, or delivering any of its feed products unless and until it had first set aside completely, and held in isolation from, all other ingredients and products in its plant, all drugs, medications, and antibiotics, and unless and until it had thoroughly cleaned all mixing and manufacturing equipment in its plant in order to eliminate all traces of drugs, medications, or antibiotics in such equipment, after which it may prepare, ship, sell, and deliver nonmedicated feed products;

4. From directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, any of its medicated feed products and from directly or indirectly causing any act to be done with respect to any article of food or drug or any medicated feed product while it was held for sale after shipment in interstate commerce, unless and until (a) adequate manufacturing facilities, adequate ingredient and product identification and controls, adequate product analyses and formulas, and other precautions essential to the manufacture and preparation of wholesome and lawful medicated feed products were installed in its plant; (b) adequate facilities, controls, and precautions were established in its plant to insure that its feed products which were not declared to contain drugs, medication, or antibiotics did not in fact contain any such drugs, medication, or antibiotics, that its feed products which were declared to contain drugs, medication, protein, or antibiotics did in fact contain the specified amounts of such drugs, medication, protein, or antibiotics, and that its feed products which contained any antibiotics possessed certificates or releases therefor, issued pursuant to 507, or complied with conditions for exemption from the requirement of such certification; and (c) the Buffalo District, Food and Drug Administration, Buffalo, N.Y., had been notified that the defendant had undertaken and completed such improvements in its plant to insure the production

of wholesome, lawful, unadulterated, and properly labeled feed products, and a duly authorized representative of the Department of Health, Education, and Welfare had inspected the defendant's plant to verify that the improvements had been accomplished, and a report of the inspection and of satisfactory improvements in defendant's plant had been made to the court.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUGS FOR HUMAN USE

7783. KC 555 and KC 555 Preparation. (Inj. No. 428.)

COMPLAINT FOR INJUNCTION FILED: 3-27-62, Dist. N.J., against Kegan Research Laboratories, Inc., Englewood Cliffs, N.J., and Kegan Sarkisian, president.

ALLEGED VIOLATION: The introduction and delivery for introduction into interstate commerce, of *KC 555* and *KC 555 Preparation* which were new drugs for which no applications filed pursuant to 505(b) were effective, in that the composition of the articles of drug was such that they were not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use, under the conditions prescribed, recommended, and suggested in the labeling of such articles of drug, namely, in the treatment of malignant diseases in man.

LABEL IN PART: (Btls. of *KC 555*) "A botanical extract derived from Asian-grown plants, it is used as an adjunctive treatment in malignant diseases, and as a stimulant when you feel run-down or listless. CONTAINS: Spiritus frumentus as preservative by volume—10%, aloes, cinchona bark, gentian, rhubarb, zedoary, calumba, agaric, galangal, bryonia, calamus, angelica, myrrh, chamomile, greenlife extract, peppermint, and *KC 555* preparation. Prepared by KEGAN RESEARCH LABORATORY, INC. Englewood Cliffs New Jersey DOSE: * * * CAUTION: An overdose of *KC 555* may produce a laxative effect. * * * A NEW PREPARATION, limited by Federal Law to investigation use. CONTENTS: 8 Fluid Ounces."

METHOD OF OPERATION: (a) The defendants, Kegan Research Laboratories, Inc., and Kegan Sarkisian, caused to be produced and delivered to Dr. George S. Zuccala, at Hartford, Conn., an article of drug designated as "*KC 555 Preparation*" which was the base or concentrate for the article of drug designated as "*KC 555*";

(b) The defendants commissioned the manufacture of *KC 555* by Dr. George S. Zuccala, at Hartford, Conn., from the *KC 555 Preparation* and commissioned the packaging of *KC 555* in bottles labeled as above;

(c) Some bottles of *KC 555* as manufactured, packed, and labeled as above were shipped by Dr. George S. Zuccala directly to customers upon the order of the defendants, and other such bottles were shipped from Hartford, Conn., to the defendants at Englewood Cliffs, N.J.;

(d) At the defendants' place of business at Englewood Cliffs, N.J., the defendants accepted orders for bottles of *KC 555* by telephone, by mail, or in person; the defendants' distribution of bottles of *KC 555* from Englewood Cliffs, N.J., was usually by parcel post;

(e) The defendants sold and distributed *KC 555* for unsupervised use by members of the general public in the treatment of malignant diseases in man.

CHARGE: 505(a)—the articles were new drugs which may not be introduced into interstate commerce, since no application filed pursuant to 505(b) was effective with respect to such drugs.

DISPOSITION: On 3-27-62, the court issued a temporary restraining order enjoining the defendants from continuing the violations alleged in the complaint. On 4-9-62, the court heard argument by the parties on the Government's motion for a preliminary injunction and thereafter the court issued a preliminary injunction. On 5-11-62, the defendants served an answer to the Government's complaint for injunction.

In that answer, the defendants denied most of the allegations of the complaint except as stated in their separate defenses listed below:

"1. Defendants admit production and distribution of a preparation known as KC 555 and allege that this production and distribution were for test purposes only and not for the use of the public.

"2. Defendants deny commissioning the manufacture of KC 555 by Dr. George S. Zuccala but admit giving him permission to use the preparation for test purposes only, and permitted him to add harmless liquids for alternative preservative methods to test palatability.

"3. Defendants admit permitting Dr. George S. Zuccala to distribute said drugs to appropriate testing doctors but never to customers upon orders of the defendants or any other party.

"4. The defendants deny accepting mail orders in any cases except terminal cases, that is, in cases where all hope for the patient's recovery is lost and their own personal physicians or doctors have left them to die and then only upon request of the patients involved.

"5. The said drug KC 555 has been previously used for many years and it is not now a new drug nor is its application new. It has been used for many years, to wit, over 50 years by doctors and botanists [botanists] and by all scientific experts and further the drug has been found to be non-toxic and has been used as a tonic blood builder and so forth for over 50 years, and further said drug has not been used and is not now being used for anything more than to build up the human body for the purpose of resisting diseases."

On 2-5-63, the defendants having advised the court that they did not wish to further contest the action, a consent decree of permanent injunction was filed which permanently enjoined the defendants from directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, in violation of Section 301(d) of the Act, the article of drug designated as "*KC 555*," the article of drug designated as "*KC 555 Preparation*," or any similar article of drug, unless and until an approval of an application filed pursuant to Section 505(b) of the Act was effective with respect to each such drug.

7784. Various animal tissues and distilled water. (F.D.C. No. 49338. S. Nos. 20-908/10 X.)

QUANTITY: 8 boxes of ovary, 6 boxes of pancreas, 12 boxes of spinal marrow, 3 boxes of aorta, 8 boxes of blood, 10 boxes of bone marrow, 6 boxes of cartilage, 10 boxes of cerebral cortex, 8 boxes of cerebral hemispheres, 3 boxes of cerebral marrow, 1 box of cerebellum, 4 boxes of colon, 7 boxes of corpora cavernosa, 7 boxes of connective tissue, 2 boxes of diencephalon, 1 box of frontal lobe, 2 boxes of gallbladder, 3 boxes of heart, 2 boxes of hypothalamus, 4 boxes of pituitary, 4 boxes of kidney, 2 boxes of liver, 5 boxes of lungs, 5 boxes of medulla oblongata, 8 boxes of muscle, 1 box of lymph gland, 2 boxes of nasal mucous membrane, 2 boxes of occipital lobe, 1 box of odontoblast, 2 boxes of optic nerve, 7 boxes of ovary corpus luteum, 3 boxes of ovarian follicles, 6 boxes of parietal lobe, 9 boxes of male placenta, 6 boxes of female placenta, 1 box of

parotid, 4 boxes of skin, 7 boxes of small intestine, 7 boxes of spleen, 7 boxes of stomach, 4 boxes of suprarenal cortex, 3 boxes of whole adrenal, 6 boxes of temporal lobe, 6 boxes of testes, 2 boxes of thymus, 1 box of thalamus, 1 box of thyroid, and 4 boxes of urinary bladder, at Amarillo, Tex.

SHIPPED: Between 1-5-61 and 6-14-63, and on other dates unknown, from Laguna Beach, Calif., by Pinco, Inc.

LABEL IN PART: (Box) "Lyocell Ovary [or other material such as "Pancreas" or "Spinal Marrow"] * * * Lyophilized sheep fetal tissue for investigational purposes only. Manufactured for and Distributed by Pinco, Inc. Pharmaceuticals * * * Laguna Beach, Calif. Warning. New Drug Limited by Federal Law."

ACCOMPANYING LABELING: Package insert entitled "Lyocell Caution: Read Before Administering. (For Intra-muscular injection only.) Contra-Indications"; invoices, purchase orders, and letters from Pinco, Inc., Pharmaceuticals to the dealer, and an undated letter to the dealer on "Academy of Molecular Medicine" letterhead signed "John W. Ballard, Executive Secretary," (Ballard is also president of Pinco, Inc., Pharmaceuticals) all of which refer to the purchase and promotion of the above articles, and were received on various dates during 1961, 1962, and 1963; price lists with heading "Tag No.," "Tissue," and "Milligrams Per Vial"; printed form authorizing the dealer to administer "Cellular Therapy" to the patient signing the form; and booklets entitled "Reprinted from Archives of Pediatrics, New York * * * The Latest Developments in Dry Cell Therapy (Siccacel)," "Die Medizinische," and "Practical Manual of dry cell therapy."

RESULTS OF INVESTIGATION: Each box contained one vial labeled similarly to the box, and one vial labeled "Lyocell Tr. Sterile Distilled Non-Pyogenic H₂O Pinco, Inc. Pharmaceuticals * * * Laguna Beach, Calif."

LIBELED: 9-19-63, N. Dist. Tex.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling contained false and misleading representations that the articles were drugs for investigational use, and that the articles were produced under control and regulation of the National Institutes of Health, U.S. Department of Health, Education, and Welfare (the articles were distributed on a commercial basis and were not produced under the control and regulation of the National Institutes of Health); 502(f) (1)—the labeling of the articles failed to bear adequate directions for use in the conditions for which they were intended, and they were not exempt from such requirement; and 505(a)—when shipped, the articles were new drugs which may not be introduced or delivered for introduction into interstate commerce, since no approval of an application filed pursuant to 505(b) was effective with respect to such drugs and they were not exempt, since they did not comply with the regulations with respect to new drugs for investigational use in that (1) no sponsor had filed a "Notice of Claimed Investigational Exemption" for the articles, (2) the articles were represented to be both safe and effective for their intended uses, and (3) the articles were being commercially distributed.

DISPOSITION: 12-9-63. Default-destruction.

7785. LSD (D-lysergic acid diethylamide). (F.D.C. No. 48735. S. No. 49-036 V.)

QUANTITY: 2 1,800-cc. plastic btl., 1 150-cc. btl., and 2 glass btl., at San Francisco, Calif., in possession of Bernard Roseman and Bernard Copley, t/a Hypnosophic Institute.

SHIPPED: On unknown dates, from outside the State of California, by unknown manufacturers.

LIBELED: 4-3-63, N. Dist. Calif.

CHARGE: 502(b)—when shipped and while held for sale, the label of the article failed to bear (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents in terms of measure; 502(e)—the article failed to have a label bearing (1) the common or usual name of the drug, and (2) the common or usual name of each active ingredient; 502(f) (1)—the labeling failed to bear adequate directions for use; 502(f) (2)—the labeling failed to bear such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form, as are necessary for the protection of users; 503(b) (4)—the article was a drug subject to 503(b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and 505(a)—the article was a new drug within the meaning of the law, and no approval of an application filed pursuant to 505(b) was effective with respect to such drug.

DISPOSITION: 5-15-63. Default—delivered to the Food and Drug Administration.

DRUG FOR VETERINARY USE

7786. Bonsul tablets. (F.D.C. No. 46507. S. No. 24-001 T.)

QUANTITY: 48 100-tablet btls. and 33 500-tablet btls., at Elyria, Ohio.

SHIPPED: 9-29-61, from Kansas City, Mo., by Veterinary Laboratories, Inc.

LABEL IN PART: (Btl.) "Bonsul—Brand of Sulfadimethoxine (2,4-Dimethoxy-6, Sulfanilamido-1, 3-Diazine) 250 Mg. for veterinary use only as an aid in the treatment of bacterial infections in dogs and cats—Amco Drug Products Co., Inc.—Sole Distributor, North Olmsted, Ohio."

LIBELED: 10-31-61, N. Dist. Ohio.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since an application filed pursuant to 505(b) was not in effect with respect to such article.

DISPOSITION: 12-8-61. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE FOR WHICH NONE HAD BEEN ISSUED

DRUGS FOR HUMAN USE

7787. Various prescription drugs. (F.D.C. No. 47911. S. Nos. 87-701/2 T, 87-704/7 T, 87-709 T, 87-712 T.)

QUANTITY: 7,144 tablets and capsules, at Fernandina Beach, Fla., in possession of Thompson Drug Co.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Clinical Trial Supply," "Physician Sample," "Professional Sample," and "Physician's Trial Package."

RESULTS OF INVESTIGATION: Some of the articles were prescription drugs which were repacked by the dealer, Thompson Drug Co., into containers to which were affixed labels bearing brand names for the drugs as were indicative of

their manufacture outside the State of Florida, a "complimentary—not for sale" professional sample legend, and the names and addresses of manufacturers, packers, or distributors located outside the State of Florida; and some of the articles were drugs which were not yet repacked by the dealer, consisting of prescription drugs in containers which bore labels containing the brand names of drugs as were indicative of their manufacture outside the State of Florida, a "complimentary—not for sale" professional sample legend, and the names and addresses of manufacturers, packers, or distributors located outside the State of Florida.

LIBELED: On or about 8-2-62, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the words "Clinical Trial Supply," "Physician Sample," "Professional Sample," "Physician's Trial Package," and similar wording on the labels of some of the articles were false and misleading as applied to articles then in the possession of a repacker and intended for sale, and not intended for use as a "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b) (1)—some of the articles failed to bear a label containing the name or place of business of the manufacturer, packer, or distributor; 502(d)—some of the articles were for use by man, which contained derivatives of the hypnotic substance, barbituric acid, which were found to be, and designated as habit-forming, and their labels failed to bear the name and quantity or proportion of such derivatives and in juxtaposition therewith, the statement "Warning—May be habit forming"; 502(e) (2)—some of the drugs were not designated solely by a name recognized in an official compendium, and their labels failed to bear the common or usual name of each active ingredient; 502(f) (1)—the labeling of some of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were drugs subject to the provisions of 503(b) (1), and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the packages of the drugs, as required by regulations; 502(1)—some of the articles purported to be drugs composed wholly or in part of penicillin, streptomycin, chlortetracycline, bacitracin, or derivatives thereof, and they were not from batches with respect to which certificates were in effect, since the drugs had their original labeling altered or removed in whole or in part; and 503(b) (4)—some of the drugs were subject to the provisions of 503(b) (1), and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 1-24-63. Default—destruction.

DRUG FOR VETERINARY USE*

7788. Medicated feed. (F.D.C. No. 46407. S. No. 83-481 R.)

QUANTITY: 688 50-lb. bags, and 164 bales, each containing 5 10-lb. bags, at Fair Lawn, N.J., in possession of American Cyanamid Co.

SHIPPED: Between 10-1-60 and 1-30-61, from South Liberty, Mo.

LABEL IN PART: (Bag) "Aureomycin Chlortetracycline Crumbles [or "Vitamin A and D Crumbles"] For Healthier Swine, Cattle and Sheep * * * Active Drug Ingredient Chlortetracycline 2 grams per pound * * * Distributed by Agricultural Division American Cyanamid Company, New York 20, N.Y."

*See also No. 7782.

ACCOMPANYING LABELING: Booklet entitled "Aureomycin Crumbles for Healthier Swine, Cattle and Sheep" (identified "VE 7055R * * * 4/60"); sample bag reading in part "Aureomycin Crumbles"; silo-shaped floor stand reading in part "Aureomycin Take Sample * * * Healthier Profits for Dairymen Cattlemen Sheepmen Hog Raisers"; poster reading in part "Aureomycin Crumbles"; stencil reading in part "make more money with Aureomycin Crumbles"; leaflets entitled "Aureomycin Crumbles Promotion Radio Spot" and "Free Sample shows you what aureomycin crumbles can do"; and "Aureomycin Crumbles * * * VE 7136-5/60."

LIBELED: 8-28-61, Dist. N.J.

CHARGE: 502(1)—while held for sale, the article was a drug composed in part of chlortetracycline, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507, and it was not exempt from such requirements, in that the following statement (bag label) "Directions for Use: Spread recommended dose of aureomycin crumbles on top of * * * each days ration," did not provide adequate directions for use as required by the exemption regulations; and the booklet and leaflet entitled "Aureomycin Crumbles," identified "VE 7055R * * * 4/60" and "VE 7136-5/60," respectively, contained statements which represented and suggested that the article was intended for use in the treatment of mastitis in dairy herds and scouring and respiratory infections in sheep, and for use in producing a brighter eye, improved hair coat or fleece, and improved bloom in cattle and sheep, and increased milk production in dairy cattle, which uses are not provided for under the exemption regulations.

DISPOSITION: 5-23-62. Consent—claimed by American Cyanamid Co. and destroyed.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

7789. Various pharmaceutical products. (Inj. No. 437.)

COMPLAINT FOR INJUNCTION FILED: 10-18-62, Dist. Md., against Burrough Bros. Manufacturing Co., a corporation, Baltimore, Md., and Benjamin Gaboff, president.

ALLEGED VIOLATIONS: The complaint alleged that the defendants were engaged in the business of manufacturing, packing, labeling, selling, and introducing and causing to be introduced and delivering and causing to be delivered for introduction into interstate commerce, articles of food and drug; that the defendants violated the law by the shipment, as above, of various articles of drug and food which were adulterated and misbranded; and that typical drugs which were introduced or caused to be introduced or delivered or caused to be delivered for introduction into interstate commerce, by the defendants on the dates indicated, in an adulterated or misbranded condition, were the following:

(a) On February 2, 1961, *strychnine sulfate tablets*, whose label bore directions for use in a daily dose which was in excess of the safe daily dose for self-administration, and whose labeling failed to bear warnings against exceeding recommended dosages or warnings to keep out of the reach of children;

(b) On February 28, 1961, *solution potassium arsenite*, which contained 6.7% excess in the potassium arsenite prescribed by the National Formulary;

(c) On March 6, 1961, *Fenadin capsules*, whose label failed to bear warnings to keep out of reach of children and which contained 34% excess aspirin;

*See also Nos. 7785, 7787.

(d) On March 20 and 27, 1961, *nitroglycerine triturates*, which failed to meet the disintegration requirements prescribed by the United States Pharmacopeia :

(e) On March 21, 1961, *nitroglycerine, digitalis*, and *Strophanthus compound tablets*, which were 50% deficient in nitroglycerine and whose label failed to bear the proper prescription legend ;

(f) On March 21, 1961, *salol (phenyl salicylate) tablets*, whose label failed to bear the common or usual name of the active ingredient, and erroneously bore a prescription legend, and whose labeling failed to bear adequate directions for use and warnings against misuse ;

(g) On April 6, 1961, *belladonna ointment*, which was 39% deficient in the belladonna alkaloids prescribed by the National Formulary ;

(h) On March 28 and 30, 1961, *sulfadiazine tablets*, which failed to meet the disintegration requirements prescribed by the United States Pharmacopeia ;

(i) On January 6, 1961, *Elixir Bromide and Chloral*, which was 25% deficient in chloral hydrate and 19.5% deficient in potassium bromide, and whose label failed to bear the proper form of prescription legend and failed to declare the percentage of alcohol ;

(j) On March 28 and 30, 1961, *phenolated calamine lotion*, whose labeling bore false and misleading representations for use in "Inflammatory skin diseases" and failed to bear a warning against unsafe methods of application and which was 4.7% deficient in volume ;

(k) On March 28 and 30, 1961, *Milk of Bismuth*, whose labeling bore false and misleading representations for use as a protective and adsorbent in gastric and intestinal inflammation and which was 4.4% deficient in volume ;

(l) On March 6, 1961, *Elixir Tungylate*, whose label failed to bear the prescription legend required for such drug ;

(m) On March 29, 1961 and March 13, 1962, *codeine sulfate tablets*, which were deficient in codeine sulfate ;

(n) On March 1, 1962, *nitroglycerine tablets*, which were 50% deficient in nitroglycerine ;

(o) On February 20, 1962, *tincture of opium*, which was 10% deficient in the anhydrous morphine prescribed by the United States Pharmacopeia.

The complaint alleged further that the defendants were well aware that their actions were in violation of the Federal Food, Drug, and Cosmetic Act ; that Burrough Bros. Manufacturing Co. was prosecuted for, and pled guilty to, similar violations of the Pure Food and Drug Act of 1906, in 1913 [N.J. No. 3003], 1925 [N.J. No. 13231], 1933 [N.J. No. 20938], and 1937 [N.J. No. 27383] ; that on October 29, 1960, the defendants shipped 12,000 cases of various adulterated and misbranded articles which purported to be and were represented as foods for special dietary uses ; that Burrough Bros. Manufacturing Co. entered into a consent decree of condemnation and remanufactured and relabeled the articles ; that the defendants did not bring the articles into compliance with the law ; and that they shipped the articles in violation of the terms of the consent decree and were subjected to a forfeiture of their bond ; that Notices of Hearing pursuant to Section 305 of the Act [21 U.S.C. 335] were issued in 1953, 1954, 1956, 1958, and 1961, warning the defendants against further violations by reason of inadequate directions for use, inadequate warning statements, improper and absent prescription legends, false and misleading representations, and failures to meet declared potency, with respect to various articles of drug, and food ; and that despite such warnings, the defendants continued to introduce and cause to be introduced and

to deliver and cause to be delivered for introduction into interstate commerce, articles which were adulterated and misbranded.

CHARGE: 501(b)—when shipped, a number of the articles purported to be drugs, the names of which were recognized in official compendiums, namely, United States Pharmacopeia and the National Formulary, and their strength differed from and their quality fell below the standards set forth in such compendiums; 501(c)—a number of the articles were drugs not subject to 501(b) and their strength differed from, and their quality fell below, that which they purported and were represented to possess; 502(a)—the labeling of a number of the drugs contained false and misleading statements with respect to the nature and quantity of the components of such drugs; 502(a)—the labeling of a number of articles which purported to be drugs, the names of which were recognized in the United States Pharmacopeia and National Formulary, contained false and misleading statements with respect to the dosage and category for use of such drugs; 502(b) (2)—the label of a number of drugs failed to bear an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; 502(e)—the label of a number of drugs failed to bear the common or usual name of the drug and, where the drug was fabricated from two or more ingredients, the label failed to bear the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol; 502(f) (1)—a number of drugs subject to 503(b) (1), and therefore to be dispensed only upon a prescription, failed to bear adequate directions for use and were not exempt from such requirement in that the labels of such drugs failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the package of such drug; 502(f) (2)—the labeling of a number of drugs which were described, or which contained components described, by the regulations which set forth statements regarding warnings on drugs for human use for over-the-counter sale, failed to bear warnings against use in those pathological conditions or by children where the use of such drugs may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as were necessary for the protection of users; 503(b) (4)—the label of a number of drugs subject to 503(b) (1), and therefore to be dispensed only upon a prescription, failed to bear, at a time prior to dispensing, the statement "Caution: Federal law prohibits dispensing without prescription"; 503(b) (4)—the label of a number of drugs to which 503(b) (1) did not apply, wrongfully bore the statement "Caution: Federal law prohibits dispensing without prescription."

A number of foods for special dietary use were alleged to be adulterated and misbranded, as reported in notices of judgment on foods.

DISPOSITION: On 10-18-62, the court issued a temporary restraining order. On 12-4-62, a consent decree of permanent injunction was filed which perpetually restrained and enjoined the defendants from directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, in violation of the law, any article of drug:

(a) That was adulterated in that its strength differed from or its quality fell below the standard set forth in an official compendium;

(b) That was adulterated in that its strength differed from, or its quality fell below, that which it purported and was represented to possess;

(c) That was misbranded because of false and misleading statements in its labeling with respect to the nature and quantity of the ingredients contained therein;

(d) That purported to be a drug, the name of which was recognized in the United States Pharmacopeia or National Formulary, and was misbranded because of false and misleading statements in its labeling with respect to the dosage and category for use of such drugs;

(e) That was in package form, and was misbranded in that its label failed to bear an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;

(f) That was not designated solely by a name recognized in an official compendium, and was misbranded in that the label of the drug failed to bear the common or usual name of the drug or, where the drug was fabricated from two or more ingredients, in that the label of the drug failed to bear the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol;

(g) That was a drug subject to 503(b)(1), and was therefore a drug to be dispensed only upon a prescription, and was misbranded in that the label of the drug failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the package of the drug;

(h) That was a drug described, or contained a component described, by the regulations which set forth statements regarding warnings on drugs for human use for over-the-counter sale, and was misbranded in that the labeling of the drug failed to bear adequate warnings against use in those pathological conditions or by children where the use of such drugs may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as were necessary for the protection of users;

(i) That was a drug subject to 503(b)(1), and was therefore a drug to be dispensed only upon a prescription, and was misbranded because the label of the drug failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; or

(j) That was a drug to which 503(b)(1) did not apply, and was therefore a drug for over-the-counter sale, to be dispensed without a prescription, and was misbranded because the label of the drug bore a prescription caution statement.

The decree also perpetually restrained and enjoined the defendants from directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, in violation of the law any article of food:

(a) That purported to be, and was represented as, a food for special dietary use, and was adulterated in that a valuable constituent had been in whole or in part omitted or abstracted therefrom; or

(b) That purported to be, and was represented as, a food for special dietary use, and was misbranded in that its labeling was false and misleading in particulars concerning its vitamins, minerals, and other dietary properties.

The decree further perpetually restrained and enjoined the defendants from directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, any article of food or drug unless:

(a) A separate identification of each lot of raw materials was recorded as the raw materials were received at the defendant's plant;

(b) Batches of foods or drugs were manufactured from complete production orders and in the quantities specified by such orders;

(c) Representative samples of raw materials and finished products were taken and separately, distinctly, and certainly identified;

(d) Representative samples were retained for not less than the time reasonably necessary for the distribution and use of the sampled, finished product and the finished product incorporating the sampled raw materials;

(e) Manufacturing records were maintained so that each lot or batch of drugs or foods manufactured, processed, relabeled, or repacked was so identified that the complete manufacturing, packing, and labeling history of each package of drug or food was clearly recorded;

(f) Each batch or lot of drugs or foods manufactured, processed, relabeled, or repacked is separately, distinctly, certainly, and securely identified at all times and during all stages of manufacture, processing, relabeling, or repackaging; and

(g) Representatives of the Food and Drug Administration of the Department of Health, Education, and Welfare were given free access to all records and controls pertaining to (1) the receipt of all raw materials or lots of drugs or foods for manufacturing, processing, repacking, or relabeling, (2) the manufacturing, processing, repacking, or relabeling of all lots or batches of foods and drugs, and (3) the distribution of all batches or lots of foods and drugs whether interstate or intrastate, including, but not limited to, the records and controls embodying all of the herein listed safeguards for interstate commerce considered necessary for the maintenance of current good pharmaceutical manufacturing practice.

7790. Various prescription drugs. (F.D.C. No. 49518. S. Nos. 5-889/98 X.)

QUANTITY: 5 100-tablet btl., 4 300-tablet btl., 3 200-tablet btl., 1 150-tablet btl., 2 500-tablet btl., and 1 50-tablet btl., and 2 boxes of 50 packets of various drugs, at Baltimore, Md., in possession of J. Weiner & Co.

SHIPPED: On unknown dates, from outside the State of Maryland, by various drug handlers.

LABEL IN PART: (Some labels) "Physician Samples" and "Starter Sample."

RESULTS OF INVESTIGATION: Some of the articles were prescription drugs repacked by the dealer, J. Weiner & Co., into containers, some of which had labels bearing brand names indicative of manufacture outside the State of Maryland or had the appearance of such brand name articles; and some of the articles were prescription drugs which were not yet repacked, originally intended for use as samples, and still in their original packages bearing the names and addresses of manufacturers, packers, or distributors located outside the State of Maryland.

LIBELED: 11-20-63, Dist. Md.

CHARGE: Articles not repacked, 502(a)—while held for sale, the words "Physician Samples," "Starter Sample," and similar wording on the articles were false and misleading as applied to articles then in the possession of a repacker and intended for sale and not then intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs.

Repacked articles, 502(b)—while held for sale, the articles failed to bear a label containing (1) the name and place of business of the manufacturer,

packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(f) (1)—the labeling of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were drugs subject to the provisions of 503(b) (1), and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history of the packages of the drugs as required by regulations; and 503(b) (4)—in that they were subject to the provisions of 503(b) (1), and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; 502(e) (1) (A) (i)—the repacked articles in unlabeled containers failed to bear labels containing the common or usual names of the articles of drug.

Some repacked articles having the appearance of "Roniacol Timespans," 502(a)—the label statements "Librium" and "Enduron" were false and misleading as applied to an article which did not consist of Librium tablets and Enduron tablets.

DISPOSITION: 12-19-63. Default—destruction.

7791. Sargon Pills and Urganin tablets. (F.D.C. No. 49122. S. Nos. 74-962 V, 74-965 V.)

QUANTITY: 1 95,000-tablet drum, 1 25,000-tablet drum, and 22 pkgs., each containing 12 individually ctnd. 40-tablet btl. of *Sargon Pills*; and 1 10,000-tablet drum, 6 pkgs., each containing 12 individually ctnd. 100-tablet btl., and 46 500-tablet btl. of *Urganin tablets*, at Warren, Pa., in possession of Myers Laboratories, Inc.

SHIPPED: 10-30-62 and 1-8-63, from St. Louis, Mo., by Private Formulae, Inc., and from Bryan, Ohio, by Paul B. Elder Co.

LABELS IN PART: (Drum) "S.C. Red Tablet Each tablet contains * * * Laxative Dosage: * * * Warning * * * Mfd. for Myers Laboratories, Inc. Warren, Pa. by Private Formulae, Inc. * * * St. Louis 15, Mo."; (ctn.) "*Sargon Soft Mass Pills Stimulate Flow of Bile Effective Intestine Eliminant Contains to each pill: Powdered Extract Belladonna Leaves $\frac{1}{12}$ gr. * * * Phenolphthalein Sodium Salicylate Bile Salts, Aloin Distributed by Myers Laboratories, Inc. Warren, Pennsylvania*"; (drum) "*Manufactured for Myers Laboratories, Inc. Warren Pa. * * * Urganin (Chocolate Color) Contains Urganin Powder * * * Supplied by customer and equals 1.5 U.S.P. Digitalis Units per tablet. Cardiotonic Usual Dose (Maintenance) 1 tablet daily * * * Private Formula Division of Paul B. Elder Company * * * Bryan, Ohio*"; and (ctn.) "*Urganin Contains two of the Cardio-Active Glycosides of Squill (Urginea Maritima) Caution To be used only by or on the prescription of a physician. Distributed exclusively by Myers Laboratories, Inc. Warren, Pennsylvania Warning.*"

RESULTS OF INVESTIGATION: Some of the bulk tablets and pills had been repacked into the bottles by the dealer.

LIBELED: 7-19-63, W. Dist. Pa.

CHARGE: *Sargon Pills*, 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective in overcoming headaches, sour stomach, gas, billiousness, poor appetite, and sluggish feeling due to failure of bile production; and 502(f) (2)—when shipped and while held for sale, the article contained belladonna, and its label failed to bear the warning that the article was not to be used

by elderly persons or by children under 6 years of age unless directed by a physician, and the further caution not to exceed the recommended dosage and that if dryness of the mouth occurs, dosage is to be decreased, and use is to be discontinued if rapid pulse, dizziness, or blurring of vision occurs; in that the article contained phenolphthalein and its label failed to bear the warning that if skin rash appears to discontinue use of the article; and in that the article contained sodium salicylate, and its label failed to bear the warning that it be kept out of the reach of children.

Urginin tablets, 502(f) (1)—when shipped and while held for sale, the labeling of the article failed to bear adequate directions for use and it was not exempt from that requirement, since the label failed to bear adequate information for its use including effects and any relevant hazards, contraindications, and side effects and precautions under which practitioners can use the drug safely and for the purpose for which it was intended, including all the purposes for which it was advertised or represented in its labeling; 503(b) (4)—while held for sale, the article was a drug subject to the provisions of 503(b) (1), and its labeling failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 8-28-63. Consent—claimed by Myers Laboratories, Inc., for re-labeling.

7792. Prenatal tablets. (F.D.C. No. 48652. S. No. 61-668 V.)

QUANTITY: 743 btls. at Fort Sam Houston, Tex.

SHIPPED: 3-15-62, from Philadelphia, Pa., by Pace Pharmacal Co., Inc.

LABEL IN PART: (Btl.) "Prenatal Tablets * * * Each Tablet Contains: * * * Ascorbic Acid (Vit. C) 100.0 Mg. * * * 100 tablets * * * Control No. 202100 [or "2664"]."

RESULTS OF INVESTIGATION: Analysis showed the article to be a coated tablet containing, in code 202100, not less than the declared amount of vitamin C and, in code 2664, approximately 75 percent of the declared amount of vitamin C. Testing for tablet disintegration by use of methods described in the United States Pharmacopeia, an official compendium, of 6 tablets of each code showed that all 6 tablets, coded 2664, remained intact after 1 hour in simulated gastric fluid test solution and 7 hours in simulated intestinal fluid test solution; and of the tablets, coded 202100, all 6 tablets remained intact after a 1-hour treatment in simulated gastric fluid test solution and after 2 hours' treatment in simulated intestinal fluid test solution; 2 of 6 tablets disintegrated after 2½ hours' treatment in simulated intestinal fluid test solution and 7 hours were required to disintegrate all 6 tablets in treatment in simulated intestinal fluid test solution.

LIBELED: 2-26-63, W. Dist. Tex.

CHARGE: 501(c)—when shipped and while held for sale, the strength of the article differed from that which it was purported to possess, since it contained (code 2664) approximately 75 percent of the declared amount of vitamin C; and in that its quality differed from that which it was purported to possess, since the article (both codes) failed to disintegrate to permit the adequate assimilation of its active ingredients on administration; 502(a)—the label statement "Ascorbic Acid (Vit. C) 100.0 Mg." was false and misleading as applied to a product containing less than the declared amount of vitamin C; 502(a)—in that its label, considered in its entirety, represented and suggested that the active ingredients of the article as normally administered are assim-

ilable in the human body, which representations and suggestions are false and misleading, since the article failed to disintegrate so as to permit assimilation of its active ingredients; and 503(b)(4)—in that it was a drug which was not subject to the provisions of 503(b)(1), and its label bore the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 6-26-63. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS AND DEVICES FOR HUMAN USE*

7793. Thorson's Soap Lake preparations. (Inj. No. 477.)

COMPLAINT FOR INJUNCTION FILED: 12-13-63, E. Dist. Wash., against Roxie Thorson, t/a Thorson's Soap Lake Products Co., Soap Lake, Wash.

ALLEGED VIOLATIONS: The complaint alleged that the defendant was engaged in the production and distribution of various articles consisting of *Thorson's Soap Lake Salts*, *Thorson's Effervescent Soap Lake Salts*, *Thorson's Concentrated Soap Lake Water*, and *Thorson's Soap Lake Ointment*, which were drugs; and that the defendant was shipping in interstate commerce, such drugs which were accompanied by leaflets relating to the drugs and which were misbranded.

LABELS IN PART: "THORSON'S Solar Evaporated Soap Lake Salts * * * Directions for Making Soap Lake Salts Water: For internal purposes. * * * These Soap Lake Salts Contain: Alumina and Iron Oxide Calcium Sulphate Calcium Carbonate Magnesium Sulphate Sodium Sulphate Sodium Chloride Sodium Carbonate Potassium Carbonate Lithium Sulphate Eye Bath * * * Nasal Douche";

"THORSON'S Effervescent SOAP LAKE SALTS ACTIVE INGREDIENTS: Bicarbonate of Soda Tartaric Acid Citric Acid Sugar Soap Lake Salts * * * USES Made and put up for the relief of Gas on the Stomach, Sour Stomach. Directions";

"THORSON'S CONCENTRATED SOAP LAKE WATER DIRECTIONS: Use as a nasal douche * * * MINOR IRRITATIONS OF THE THROAT * * * IVY, OAK POISONINGS * * * MUSCULAR SORENESS, due to exposure, exertion, or fatigue * * * FOR SIMPLE RINGWORM * * * MINOR IRRITATIONS OF THE SKIN"; and "THORSON'S SOAP LAKE OINTMENT * * * USES * * * FOR MINOR SKIN IRRITATIONS DIRECTIONS: * * * Active ingredients: Soap Lake Salts, Amber Petrolatum and Powdered Zinc Oxide."

ACCOMPANYING LABELING: Leaflets entitled "Some Won't Die," "Thorson's Soap Lake Products," and "Soap Lake Salts."

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for treating Buerger's disease (Thrombo-angiitis obliterans), Raynaud's and allied diseases of the circulatory system, gangrene conditions, wounds, rheumatism, acute alcoholism, cerebral hemorrhage, stroke, laxative elimination, bile flow and restoring an alkaline balance to the body, stimulation of perspiration and cleansing of the skin, skin troubles, eczema, neuritis, arthritis, sciatica, lumbago, stiffness, muscular pains, nervousness, many forms of digestive and intestinal disturbances, athlete's foot, ringworm, psoriasis, poison

*See also Nos. 7781, 7784, 7785, 7787, 7789-7791.

rash, dermatitis, metal poisoning, ulcers, irritations of the skin, sore muscles, toning up the system, and relaxing tired muscles and nerves generally, neutralizing and eliminating toxic materials from the body, sour stomach, gas in stomach, heartburn, minor skin irritations, minor irritations of the throat, and ivy and oak poisonings; and 502 (f) (1)—the labeling of the articles failed to bear adequate directions for use for the conditions and purposes for which they were intended.

DISPOSITION: On 12-23-63, the defendant having consented, a consent decree of permanent injunction was filed. The decree perpetually enjoined and restrained the defendant from directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, in violation of the law, the articles of drug consisting of *Soap Lake Salts, Effervescent Soap Lake Salts, Concentrated Soap Lake Water, Soap Lake Ointment*, or any similar articles of drug—

(a) Which were accompanied by the leaflets entitled "Some Won't Die," "Thorson's Soap Lake Products," and "Soap Lake Salts," or by any other written, printed, or graphic matter substantially to the same effect;

(b) Which bore or were accompanied by any written, printed, or graphic matter which stated, suggested, represented, or implied that such articles were adequate and effective for treating the various diseases, conditions, and symptoms enumerated above, or which were otherwise false and misleading; and

(c) Which did not bear or were not accompanied by labeling which bore adequate directions for use of the articles for the conditions and purposes for which they were intended.

7794. Vanul aqueous suspension. (Inj. No. 470.)

COMPLAINT FOR INJUNCTION FILED: 6-24-63, Dist. N.J., against Vanguard Pharmaceutical Corp., Cedar Grove, N.J., and Kenneth E. Brooks, president.

LABEL IN PART: "Vanul * * * A Licorice-peppermint flavored aqueous suspension of vegetable mucilage with tincture of belladonna * * * Each tablespoonful (15 cc) dose contains: Vegetable mucilage 2 cc Tincture of belladonna 0.3 cc Fluidextract of glycyrrhiza 0.35."

ACCOMPANYING LABELING: Brochures entitled "Vanul New discovery in the treatment of Gastric and Duodenal Ulcers"; signs and display placards reading in part "ULCERS" Adequate treatment is one which alters the abnormal acid peptic activity," "ULCERS? Come In For Free Booklet Describing New 6-Week Treatment with amazing VANUL," "RESULTS: Total of 408 Case Histories Has Been Received From Physicians Throughout The Country," "Ask Your Physician about VANUL The New Therapy! Come In For Free Booklet!" and "VANUL * * * DOES NOT INTERFERE WITH NORMAL DIET!"

ALLEGED VIOLATION: The complaint alleged that Vanguard International Corp., of Deer Park, N.Y., which produced a single drug product, *Vanul*, caused the defendant corporation to be formed in the State of New Jersey in October 1958, as its sales organization; that the defendants had been and were engaged in the business of distributing, selling, introducing, and shipping in interstate commerce, and of holding for sale after shipment in interstate commerce, an article of drug designated by the name "*Vanul*," and labeled in part as above.

The complaint alleged that the drug, when shipped and while held for sale, was accompanied by the above-mentioned accompanying labeling relating to the drug; that the defendants were well aware that their activities were violative of the law; that on August 28, 1958, the Food and Drug Administration informed the producers of *Vanul* that the drug could not be marketed without a prescription legend on the label of the drug; that, at that time, the propriety of the claims made for *Vanul* for the treatment of ulcers was questioned; that on March 31, 1959 and April 7, 1959, a representative of the producers of *Vanul* personally conferred in Washington, D.C., with officials of the Food and Drug Administration, and was refused permission to label the drug "for sale without prescription" and was further advised that the product was not considered as an antacid; that in October 1960, a number of articles of *Vanul* were seized in the Southern District of New York and a default decree of condemnation and destruction was entered on November 3, 1960; that on June 6, 1961, a hearing was held at which time defendants were represented by counsel and admitted that the above brochures describing the use and benefit of the drug, *Vanul*, were delivered in interstate commerce by defendants; and that, on May 22, 1962, an Information was filed in the District of New Jersey against the defendants.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for gastric and duodenal ulcers; and 502(f) (1)—the labeling of the article failed to bear adequate directions for the unsupervised lay-use of the drug for conditions self-diagnosed by the laity as gastric and duodenal ulcers, in that adequate directions for such unsupervised lay-use cannot be written.

DISPOSITION: On 6-28-63, the defendants having consented, the court entered a decree of permanent injunction perpetually restraining and enjoining them:

(1) From directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, in violation of the law, any articles of drug known as "*Vanul*," or any similar drug, and labeled in part as in the above label, which were misbranded within the meaning of 502(a) and 502(f) (1) and which

(a) were accompanied by the above accompanying labeling or by any written, printed, or graphic matter substantially to the same effect;

(b) bore or were accompanied by any written, printed, or graphic matter which stated, suggested, represented, or implied that such drug was an adequate and effective treatment for gastric and duodenal ulcers or which was otherwise false and misleading; and

(c) bore or were accompanied by labeling containing directions for unsupervised lay-use of such drug for conditions self-diagnosed by the laity as gastric and duodenal ulcers;

(2) From directly or indirectly causing any act to be done with respect to any articles of the drug, *Vanul*, or any similar drug, while such articles of drug were held for sale after shipment in interstate commerce, which act resulted in any article of drug being misbranded within the meaning of 502(a) and 502(f) (1) by reason of

(a) being accompanied by the above-mentioned accompanying labeling, or by any written, printed, or graphic matter substantially to the same effect;

(b) bearing or being accompanied by any written, printed, or graphic matter which stated, suggested, represented, or implied that such drug

was an adequate and effective treatment for gastric and duodenal ulcers or which was otherwise false and misleading; and

- (c) bearing or being accompanied by labeling containing directions for unsupervised lay-use of such drug for gastric and duodenal ulcers; and

(3) From shipping, selling, or delivering in interstate commerce, any of the drug, *Vanul*, or any similar drug, from their existing stocks and that all such existing stocks of *Vanul* and labeling for such drug in their possession were to be destroyed under the supervision of an authorized representative of the Food and Drug Administration, Department of Health, Education, and Welfare; costs of such supervision to be paid by defendants.

7795. Vanul aqueous suspension. (F.D.C. No. 47076. S. No. 32-780 R.)

INFORMATION FILED: 5-13-63, Dist. N.J., against Vanguard Pharmaceutical Corp., Cedar Grove, N.J.

SHIPPED: 8-23-60, from Cedar Grove, N.J., to New York, N.Y.

LABEL IN PART: (Btls.) "16 Ounces Vanul A licorice-peppermint flavored aqueous suspension of vegetable mucilage with tincture of belladonna. Indications and Actions: * * * Distributed by Vanguard Pharmaceutical Corp. Cedar Grove, N.J. Each tablespoonful (15 cc) dose contains: Vegetable mucilage 2 cc Tincture of belladonna 0.3 cc Fluidextract of glycyrrhiza 0.35."

ACCOMPANYING LABELING: Brochures entitled "Vanul New discovery in the treatment of Gastric and Duodenal Ulcers"; signs and display cards reading in part "ULCERS Adequate treatment is one which alters the abnormal acid peptic activity," "ULCERS? Come In For Free Booklet Describing New 6-Week Treatment with amazing VANUL," "RESULTS: Total of 408 Case Histories Has Been Received From Physicians Throughout The Country," "Ask Your Physician about VANUL The New Therapy! Come in for Free Booklet!" and "VANUL * * * DOES NOT INTERFERE WITH NORMAL DIET!"

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for gastric and duodenal ulcers; and 502(f) (1)—the labeling of the article failed to bear adequate directions for the unsupervised lay-use of the article for conditions self-diagnosed by the laity as gastric and duodenal ulcers, in that adequate directions for such unsupervised lay-use cannot be written.

PLEA: Guilty.

DISPOSITION: 9-13-63. \$200 fine.

7796. Prescription drugs. (F.D.C. No. 49261. S. Nos. 31-722/8 X.)

QUANTITY: 1 drum containing 5,400 tablets and 15 100-tablet btls. of *methyl-testosterone*; 1 drum containing 21,700 tablets and 12 100-tablet btls. of *stilbestrol*; 1 drum containing 16,000 capsules and 3 100-capsules btls. of *Dexabarb #1*; 1 drum of 40,000 capsules and 23 100-capsule btls. of *dextro-amphetamine sulfate with amobarbital (Dexabarb #3)*; 1 drum containing 14,000 tablets and 8 1,000-tablet btls. of *dextro-amphetamine sulfate (Yellow)*; 1 drum containing 32,000 tablets and 4 1,000-tablet btls. of *reserpine alkaloid* (0.1 mg.); 1 drum containing 10,950 tablets and 16 100-tablet btls. of *Rauwolfia serpentina*, at El Monte, Calif., in possession of Hilly Medicinal Products, Inc.

SHIPPED: Between 1956 and 6-20-63, from Long Island City, N.Y., and Philadelphia, Pa.

LABEL IN PART: (Drum) "Methyl Testosterone 10 mg.," (btl.) "Sublingual * * * Methyl Testosterone 10 mg. Caution * * * Hilly Medicinal Products Sole Distributors Pasadena 8, Calif.,"; (drum) "Stilbestrol tablets (Diethylstilbesterol) 25.0 mg. Caution * * * Warning * * * Directions," (btl.) "Hilly Stilbesterol 25.0 mg. Caution * * * Hilly Med. Products East Pasadena 8, Calif.,"; (drum) "Dexabarb #1," (btl.) "Granucaps Hilly Dexabarb #1 * * * Warning * * * Caution * * * Hilly Medicinal Products Sole Distributors East Pasadena 8, Calif.,"; (drum) "Dextro Amphetamine 15 mg. with Amobarbital 90 mg.," (btl.) "Granucaps Hilly Dexabarb #3 * * * Hilly Medicinal Products Sole Distributors East Pasadena 8, Calif.,"; (drum) "Dextro Amphetamine Sulfate Tablets 5 mg.," (btl.) "Amphetamine Sulfate Dextro-Yellow 5 mg. * * * Hilly Medicinal Products Sole Distributors East Pasadena 8, Calif.,"; (drum) "Reserpine Alkaloid 0.1 Mgm.," (btl.) "Reserpine Alkaloid 0.1 mgm. * * * Hilly Medicinal Products Sole Distributors East Pasadena, Calif.,"; (drum) "Rauwolfia Serpentina * * * 100 Mgm.," (btl.) "Rauwolfia Serpentina 100 mg. * * * Hilly Medicinal Products Sole Distributors East Pasadena 8, Calif."

RESULTS OF INVESTIGATION: The articles were shipped in bulk, and were repacked and labeled by the dealer.

LIBELED: 9-12-63, S. Dist. Calif.

CHARGE: 502(f) (1)—while held for sale, the labeling of the articles failed to bear adequate directions for use, and they were not exempt from such requirement, since their labeling failed to conform to regulations that their labeling bear adequate information for their use, including relevant hazards, contraindications, side effects, and precautions under which licensed practitioners can use the drugs safely and for all their intended purposes.

DISPOSITION: 3-31-64. Consent—claimed by Hilly Medicinal Products, Inc., and released under bond for relabeling.

7797. Various prescription drugs. (F.D.C. No. 49106. S. Nos. 78-337/40 V, 80-221/2 V, 80-224/5 V, 80-235 V, 80-238/40 V.)

QUANTITY: 1 unlabeled 1,000-capsule btl. of 1.51-gr. *pentobarbital sodium capsules*, 1 unlabeled 1,000-capsule btl. of 1.64-gr. *pentobarbital sodium capsules*, 6 unlabeled 1,000-tablet btl. containing 1.44-gr. *phenobarbital tablets*, 20 unlabeled 1,000-tablet btl. containing 9.86-mg. *amphetamine sulfate tablets*, 1 unlabeled 1,000-capsule btl. containing 1.46-gr. *secobarbital sodium capsules*, 2 unlabeled 100-tablet btl. containing 279,396-unit *penicillin G potassium tablets*, 3 50-capsule pkgs. marked "Quills 50" containing 13.25-mg. *dextro-amphetamine sulfate capsules*, 1 25-capsule pkg. marked "Dex 25" containing 13.61-mg. *dextro-amphetamine sulfate capsules*, 2 110-tablet btl. labeled in part "Buffered" containing 272,011-unit *penicillin G potassium tablets*, 6 unlabeled 1,000-tablet btl. containing 10.54-mg. *amphetamine sulfate tablets*, 2 unlabeled 1,000-tablet btl. containing 5.01-mg. *dextro-amphetamine sulfate tablets*, and 1 unlabeled 50-capsule vial containing 1.59-gr. *pentobarbital sodium capsules*, at Lakewood, Ohio.

SHIPPED: Prior to 4-30-63, from Philadelphia, Pa., or Brooklyn, N.Y.

RESULTS OF INVESTIGATION: The articles had been found in the possession of individuals arrested by an officer of the Cleveland, Ohio, police department and were held by the local authorities pending the disposition of the arrested individuals.

LIBELED: 8-9-63, N. Dist. Ohio.

CHARGE: 502(f) (1)—while held for sale, the labeling of the articles failed to bear adequate directions for use and they were not exempt from that requirement, since they were prescription drugs which were held for sale by persons not lawfully engaged in distributing and dispensing prescription drugs.

DISPOSITION: 9-12-63. Default—destruction.

7798. Throat lozenges. (F.D.C. No. 49381. S. No. 39-268 X.)

QUANTITY: 416 4-tablet pkgs., at Rio Piedras, P.R., in possession of Cobian Enterprises.

SHIPPED: 4-19-63, from Newark, N.J.

LABEL IN PART: "Relyf Antibiotic Anesthetic * * * Cobian Enterprises Miami, Florida."

ACCOMPANYING LABELING: Display card reading in part "?Dolor de Garganta? ?Irritacion en la Boca? ?Tos? !Alivio Inmediato! Relyf Anestésico Sabor Agradable Relief for Sore throat"; and leaflet reading in part "Relyf ?Dolor De Garganta . . . ? ?Irritacion De La Boca * * * Exija RELYF con su jirafa al lado. * * * La Jirafa es su garantia."

RESULTS OF INVESTIGATION: The accompanying labeling had been printed on order of the dealer and was used as promotional material. The shipping carton indicated that the article contained thyrothricin (2 mg.) and benzocaine (10 mg.) in each lozenge.

LIBELED: 10-16-63, Dist. P.R.

CHARGE: 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective as a treatment for sore throat, mouth irritation, cough, toothache, pain of false dentures, and infections of the throat; 502(b) (1)—the article failed to bear the proper address of the distributing firm, since such firm was not located at the address shown on the package label; 502(e) (1) (A) (ii)—the label of the article failed to bear the name and quantity of each active ingredient; 502(f) (1)—the labeling of the article failed to bear adequate directions for use; and 502(f) (2)—the labeling of the article failed to bear warning statements with reference to anesthetic- and antibiotic-containing drugs.

DISPOSITION: 12-13-63. Default—destruction.

7799. Compound cathartic pills. (F.D.C. No. 48947. S. No. 15-770 V.)

QUANTITY: 76 ctns., each containing 12 8-pill pkgs., at Nashville, Tenn., in possession of Cumberland Manufacturing Co.

SHIPPED: 11-17-60, from St. Louis, Mo.

LABEL IN PART: (Pkg.) "C C Pills 8 Pills Per Package Compound Carthartic Pills N.F. Active Ingredients: Compound Colocynth Ext. 80 mg. Calomel 60 mg. Jalep Resin 20 mg. Gamboge 1.5 mg. Dose for Adults * * * Packed by Cumberland Mfg. Co. Nashville, Tenn."

RESULTS OF INVESTIGATION: The article had been repacked from bulk drums by the dealer. Examination showed that the article contained approximately 20 percent of mild mercurous chloride (calomel) specified by the National Formulary for the article.

LIBELED: 5-6-63, M. Dist. Tenn.

CHARGE: 501(b)—while held for sale, the article was represented as a drug, "Compound Cathartic Pills," the name of which is recognized in the National

Formulary, an official compendium, and its strength differed from and its quality fell below the standard set forth in such compendium; 502(a)—the name "Compound Carthartic Pills N.F." was false and misleading as applied to a product which did not comply with the National Formulary standard for such product; and 502(f) (2)—the labeling of the article failed to warn that frequent or prolonged use of the article may result in dependence on laxatives, and serious mercury poisoning.

DISPOSITION: 6-19-63. Default—destruction.

7800. **Supainex capsules and Supab-Na-Sal tablets.** (F.D.C. No. 45268. S. Nos. 32-051 R, 32-053 R.)

QUANTITY: 8 cases, each containing 48 100-capsule btl., of *Supainex*, and 38 100-tablet btl. of *Supab-Na-Sal*, at New Orleans, La.

SHIPPED: 6-26-59 and 4-26-60, from St. Louis, Mo., by K V Pharmacal Co.

LABEL IN PART: (Btl.) "SUPAINEX Analgesic-Antipyretic With Vitamin 'C' Each Capsule contains: Acetylsalicylic Acid * * * Acetophenetidin * * * Caffeine * * * Ascorbic Acid (Vitamin C) * * * Distributed by Superior Pharmacal Corp. * * * Dosage * * * Action and Uses" and "No. 8 SUPAB-NA-SAL Each Enteric Coated Tablet contains: Sodium Salicylate/Sodium Para-Aminobenzoic Acid * * * Ascorbic Acid (Vitamin C) * * * Dosage: * * * Superior Pharmacal Corporation Distributors * * * Indications."

LIBELED: 12-8-60, E. Dist. La.

CHARGE: *Supainex capsules*, 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for pain, fever, headache, neuralgia, common cold, influenza, gripe, rheumatic conditions, and dysmenorrhea; both articles, 502(f) (2)—when shipped, their labels failed to bear a statement that the articles should be kept out of the reach of children, and their labeling failed to warn that if pain persisted for more than 10 days or redness was present or in conditions affecting children under 12 years of age, that a physician should be consulted immediately.

DISPOSITION: The articles were claimed by Superior Pharmacal Corp., New Orleans, La., and on 8-3-61, a consent decree of condemnation providing for relabeling was entered. On 10-17-63, claimant having failed to repossess the articles, a default was entered and the bond forfeited to the extent sufficient to cover court costs.

7801. **Various dietary supplements.** (F.D.C. No. 48997. S. Nos. 74-945/6 V, 74-948/50 V, 74-952 V.)

QUANTITY: 4,000 *Gest-O-Zyme tablets* in 100-tablet btl.; 12,000 *Pep-O-Vite tablets* in a bulk drum and 4 30-tablet btl.; 3 16,677-tablet drums of *Super Insta' Protein Wafers*; 3 25,000-tablet drums, 1 24,000-tablet drum, 31 30-tablet btl., and 10 60-tablet btl., of *Super-Acto-C tablets*; 1 7,925-capsule drum, 25 100-tablet btl., and 11 200-tablet btl., of *Super Optimum capsules*; and 26 cases, each containing 24 100-tablet btl., of *Geri Bio Vites Vitamin Formula tablets*, at Venetia, Pa., in possession of Nu-Age Biorganic Products.

SHIPPED: Between 9-28-62 and 6-4-63, from Freeport, Inwood, and Brooklyn, N.Y.

LABEL IN PART: (Btls.) "100 Coated Tablets Gest-O-Zyme * * * combination of digestive enzymes and supporting factors * * * Manufactured for and distributed by Nu-Age Biorganic Products Venetia, Pennsylvania * * * Directions (as an aid to digestion)"; "Pep-O-Vite Multi Vitamins * * * A natural dietary supplement providing multi-vitamins, enzymes, and vitagenic natural ingredients * * * Protein Glazed—Sugar Free Manufactured For and Distributed by Geriatrex Products Co. * * * Canonsburg, Pa. Directions: As a multi-vitamin dietary supplement"; (drum) "Tasty Chewable Wafers 31 Grains Super Insta' Protein (Protein 63.1%) Natural-Organic * * * Contains: Collagen (predigested protein) 9 grams Vitamin C (from rose hips extract) 180 mg. * * * Natural Excipients and Flavoring * * * A dietary supplement of predigested protein. Manufactured for and Distributed by Geriatrex Products Co. * * * Canonsburg, Penna. Directions: For use as additional amounts of Protein to the daily dietary intake"; (btls.) "Super-Acto-C Vitamin C Natural 300 milligrams * * * Natural Vitamin C from Rose Hips Concentrate, providing 300 mg. of Natural Vitamin C coupled with the Bio-flavonoids * * * Manufactured for and Distributed by Nu-Age Biorganic Products * * * For the prevention and treatment of Vitamin C deficiency * * * Directions"; "Super Optimum Natural Dietary Supplement Providing naturally occurring Multi-Vitamins-Minerals, Organic Iron, Rose Hip Extract, Amino Acids, Vitamin B-12, Pectin, Enzymes, Liver, High Potency Yeast, Iodine, Unsaturated fatty acids and lipotropic factors in a superb combination Manufactured for and Distributed by Nu-Age Biorganic Products Venetia, Pa."; and "Natural-Organic Geri Bio Vites Vitamin Formula Important Vitamins Coupled With Digestive Enzymes * * * Nu-Age Biorganic Products Venetia, Pennsylvania."

ACCOMPANYING LABELING: Catalogs entitled "20% Discount Spring Summer Sale—Nu Age Biorganic Products" and "Geriatrex Products Company Catalog"; and repack labels for use in labeling the repackaged articles.

RESULTS OF INVESTIGATION: The articles had been shipped in bulk drums and had been repacked in part, by the dealer, into bottles labeled as above. The dealer used the above catalogs in promoting sales of the articles.

LIBELED: 6-3-63, W. Dist. Pa.; libel amended 6-11-63.

CHARGE: *Gest-O-Zyme tablets*, 502(a)—while held for sale, the name of the article and the labeling contained false and misleading representations that the article was adequate and effective to promote the digestion, assimilation, and utilization of food intake; and for the treatment and prevention of indigestion, digestive disorders, digestive deficiencies, gas pains, pressure, bloating, heartburn, discomfort after eating, and digestive conditions caused by hurry, stress, and worry; and that middle-aged and elderly people are prone to digestive disturbances; that the elderly lose their ability to make enzymes; that gastric juices decline with age; and that the article is natural.

Pep-O-Vite—multiple vitamins tablets, 502(a)—while held for sale, the name of the article, "Geriatrex Pep-O-Vite," and statements in its labeling contained false and misleading representations that the article was adequate and effective for the treatment and prevention of pus formation, sinusitis, conjunctivitis, unhealthy blood vessels, hypertension, infections, colds, tuberculosis, lesions in colon, cysts, to promote pep, and for other purposes; that the article was natural; and that the nutritional requirements of the elderly are different from adults, generally.

Super Insta' Protein Wafers (chewable), 502(a)—while held for sale, the name of the article, "Super Insta' Protein," and statements in its labeling contained false and misleading representations that the article was adequate and effective to promote strength; build muscles and body; provide quick energy; for the treatment and prevention of unhealthy gums, losing of teeth, decayed teeth, unhealthy blood vessels, and weakness of capillary walls; that it was of significant value for special dietary supplementation and therapeutic use by reason of the presence therein of protein; and that the article was natural and organic.

Super-Acto-C tablets, 502(a)—while held for sale, the name of the article, "Super-Acto-C," and statements in its labeling contained false and misleading representations that the article was adequate and effective to promote firmness and vitality of the tissues, body health, disease resistance, and a state of well-being; that the nutritional requirements of the elderly are different from adults, generally; and that the article was natural.

Super Optimum capsules, 502(a)—while held for sale, the name of the article, "Super Optimum," and statements in its labeling contained false and misleading representations that the article was adequate and effective to promote long life, sparkle in the eyes, bounce, energetic feeling, aid digestion, growth, vitality, build blood, teeth and bones, enthusiasm, glowing feeling, sound body, zest, and digestion by reason of the enzyme content; and for treatment and prevention of anemia, fatigue, rundown feeling, and loss of vigor; that the article was natural and organic; and that the article was of super-optimum content because all of the nutrients were vitalized.

Geri Bio Vites tablets, 502(a)—while held for sale, the name of the article, "Geri Bio Vites Vitamin Formula," and statements in its labeling, contained false and misleading representations that the article was adequate and effective for the treatment and prevention of premature aging, to promote digestion, feeling of fitness, to be useful, develop interest, a full, rich, rewarding life, sparkle, attractiveness, and long life; that the article was natural and organic; and that the nutritional requirements of the elderly are different from adults, generally.

All the articles, 502(f) (1)—while held for sale, the labeling of the articles failed to bear adequate directions for the diseases, conditions, and purposes for which they were intended, prescribed, and recommended in the catalogs.

DISPOSITION: 1-7-64. Consent—destruction.

7802. *Dried comfrey leaf and comfrey tablets*. (F.D.C. No. 49378. S. No. 31-776 X.)

QUANTITY: 23 8-oz. bags and 74 4-oz. bags of *dried comfrey leaf*, and 17 96-tablet boxes and 13 60-tablet btls. of *comfrey tablets*, at Riverside, Calif.

SHIPPED: On an unknown date, from Otorohanga, New Zealand, by Comfrey Supplies (N.Z.), Ltd.

LABEL IN PART: (Bag) "Vitamin Nimativ Dried Comfrey Leaf Add to boiling water and prepare as in the usual way for tea. * * * Manufactured by Comfrey Supplies (N.Z.) Ltd. * * * Otorohanga, N.Z." and "Vitamin Nimativ Dried Comfrey Leaf * * * Analysis * * * Mineral * * * Vitamin B Group * * * Manufactured by Comfrey Supplies (N.Z.) Ltd. * * * Otorohanga, N.Z."; (box) "Comfrey Tablets Energy Strength Health * * * Recommended Dose * * * Standard Analysis * * * Mineral * * * Vitamin B Group Comfrey Supplies (N.Z.) Ltd." and (btl.) "Comfrey Tablets Dose * * *

Each Tab. 5 grains Manufactured from dried Comfrey leaf * * * Comfrey Supplies (N.Z.) Ltd. * * * Otorohanga."

ACCOMPANYING LABELING: Brochures entitled "Comfrey The Wonder Plant."

LIBELED: 10-1-63, S. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective as a treatment for asthma and all bronchial complaints, heart and blood conditions, anemia, rheumatoid arthritis, and kindred complaints in all cases of malnutrition; and for veterinary uses as a cure of all internal hemorrhages, including uterine; to heal wounds; knit broken bones; internal ulcers; ruptures; pulmonary ailments; bloat; eczema; scours in mares with foals; and as a special concentrated diet for horses in training; 502(b) (2)—the article failed to bear a label containing an accurate statement of quantity of contents (60-tablet bottles); and 502(f) (1)—the labeling failed to bear adequate directions for use (tablets only).

The libel alleged also that the articles were misbranded under the provisions of the Act relating to foods, as reported in notices of judgment on foods.

DISPOSITION: 11-15-63. Default—destruction.

7803. Various devices. (Inj. No. 450.)

COMPLAINT FOR INJUNCTION FILED: 3-27-63, N. Dist. Calif., against Harry T. Saine, Morgan Hill, Calif.

CHARGE: The complaint alleged that the defendant was engaged in repairing devices which had been manufactured by the Electronic Medical Foundation, San Francisco, Calif., and which were known as the *Oscilloclast*, *Oscillotron*, *Regular Pushbutton Shortwave Oscilloclast*, *Sweep Oscillotron*, *Sinusoidal Four-In-One Shortwave Oscillotron*, *Galvanic Five-In-One Shortwave Oscillotron*, *Depolaray*, *Depolatron*, *Depolaray Chair*, *Depolatron Chair*, *Depolaray Junior*, *Electropad*, *New Depolaray Junior* and the *Blood Specimen Carriers* which were intended for use as component parts of the device designated as the *Radioscope*; and that in the normal course of the defendant's business the devices were received from owners, outside the State of California, for repair or overhauling, and when the necessary repairs had been completed the devices were returned in interstate commerce, to their owners.

The complaint alleged also that the devices, when shipped, were misbranded within the meaning of 502(f) (1) in that their labeling failed to bear adequate directions for use for the purposes for which they were intended, namely, to diagnose and treat disease conditions in man and to affect the structure and function of the body of man, since the devices had no value in affecting the structure and function of the body and adequate directions could not be given for such purpose.

The complaint alleged further that the devices had previously been adjudged misbranded and adulterated, in injunction proceedings against the manufacturers, and that the defendant, as an employee, was served with a copy of the decree enjoining the parties and their agents, servants, employees, and representatives from shipping the devices.

DISPOSITION: 3-27-63. The defendant having consented, a decree of permanent injunction was entered by the court, which enjoined the defendant from directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, and more particularly from delivering or causing to be delivered to customers and

other persons living outside the State of California, for transportation in interstate commerce, any of the above-mentioned devices, or any similar article of device, allegedly capable of producing or measuring low-power radio waves, or electromagnetic energy or low-frequency alternating magnetic energy, or any accessory component, or part of any such article, which was originally manufactured by the Electronic Medical Foundation and which was in the defendant's possession for repair or was already repaired by the defendant. The decree provided also that the defendant would:

- a. Cease any repair work currently in progress on any of the aforesaid devices;
- b. Refuse to accept any of the aforesaid devices which are sent to them for repair;
- c. Destroy all parts on hand which were of value only in the repair, reconstruction, and/or operation of any of the said devices; and
- d. Notify all known customers that he would no longer repair any of the aforesaid devices.

7804. Various devices. (F.D.C. No. 48643. S. Nos. 29-154/6 V.)

QUANTITY: 47 *Micro-Dynamometer devices*, 2 *Neurolinometer devices*, and 1 *Micro-Tabulometer device*, at Independence, Mo.

SHIPPED: On unknown dates, from Chicago, Ill., Cumberland, Wis., and Bridgeport, Conn.

RESULTS OF INVESTIGATION: Examination indicated the *Micro-Tabulometer* to be a wooden instrument cabinet containing a current meter, toggle switches, and control dials. The cabinet contained a variety of bridge circuits and simple electrical circuits for applying voltage to the body and measuring the amount of current passing through the electrodes and the body.

Investigation indicated that the *Neurolinometers* were devices housed in black, suitcase-type containers, about 15 inches long, 9¼ inches wide, and 5½ inches deep. The face of the devices contained 8 knobs variously labeled in part "ten," "one," "cervical," or "base." The device otherwise consisted of a monopolar electrode, a single-stage amplifier, and a power supply unit, the output of which was applied to a section of wire mesh attached beneath a sheet of bakelite.

Investigation also indicated that the *Micro-Dynamometers* were essentially galvanometers for measuring electrical currents and electrical potentials of small magnitude. Each device was mounted in a metal cabinet, on the face of which was a scale or meter intended to measure the flow of current in milliamperes, together with a number of dials which could be set at numbered or lettered positions. The dial settings were intended to increase or decrease the resistance to the current flowing through the device. The current which flowed and was measured by the scale or meter was generated by closing the circuit between two dissimilar metal "probes." The circuit was closed by placing the "probes" at different points on the human body by placing the "probes" together, or by immersing them in water.

LIBELED: 2-19-63, W. Dist. Mo.

CHARGE: 502(f) (1)—while held for sale, the labeling of the articles failed to bear adequate directions for use for their intended purpose of diagnosis of disease in man, since the articles were worthless for use for such purpose, and adequate directions cannot be given for the use of the articles for such purpose.

DISPOSITION: 4-4-63. Default—the *Micro-Tabulometer*, the *Neurolinometers*, and 17 *Micro-Dynameters* delivered to the Food and Drug Administration; the remaining devices destroyed.

7805. Micro-Dynameter device. (F.D.C. No. 48326. S. No. 21-426 V.)

QUANTITY: 1 device at Rexburg, Idaho.

SHIPPED: Between 9-1-58 and 9-30-58, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "For Scientific Body Analysis The Ellis Micro-Dynameter Mfd. by Ellis Research Laboratories, Inc. Chicago U.S.A."

LIBELED: 10-19-62, Dist. Idaho.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for diagnosing disease; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use, and was not entitled to any exemption from that requirement.

DISPOSITION: On or about 3-1-63, the Government served written interrogatories upon C. S. Green, D.C., in which questions concerning the possession, location, custody, and disposition of a *Micro-Dynameter* were asked. On 3-15-63, C. S. Green moved for an extension of time in which to file answers or objections to the interrogatories.

On 3-18-63, C. S. Green delivered the device to the U.S. marshal. On 3-20-63, the Government moved for a default judgment. On or about 3-22-63, the court filed *nunc pro tunc* an answer in letter-form, dated Nov. 4, 1962, from C. S. Green, and granted the motion of C. S. Green for an extension of time in which to file an answer or objections to interrogatories. On 4-9-63, the Government served written interrogatories upon C. S. Green concerning the use, purposes, and labeling of the device; and, on 8-21-63, C. S. Green filed answers to such interrogatories. On or about 10-15-63, the Government filed supplemental interrogatories upon C. S. Green and, on 1-29-64, C. S. Green filed answers to the supplemental interrogatories.

On 2-18-64, pursuant to stipulation, Dr. C. S. Green withdrew his answer and a default decree of condemnation was entered ordering the device delivered to the Food and Drug Administration for investigational purposes.

7806. Micro-Dynameter devices (5 seizure actions). (F.D.C. Nos. 47827, 47922, 47996, 48314. S. Nos. 66-968 T, 89-008 T; 63-555 T; 31-191 T, 31-936 T, 31-188/90 T, 31-476 T, 31-539/40 T, 31-934 T, 31-937/8 T, 65-176/81 T; 72-256 T.)

QUANTITY: 2 devices at Flint and Detroit, Mich.; 1 device at Stoughton, Wis.; 2 devices at San Diego and Oceanside, Calif., 15 devices at Los Angeles, Buena Park, Long Beach, Burbank, Glendale, Pomona, Joshua Tree, Huntington Park, Anaheim, Bell, and Santa Monica, Calif.; and 1 device at Bristol, Tenn.

SHIPPED: On various dates, from Chicago, Ill., by Ellis Research Laboratories, Inc.

LABEL IN PART: "For Scientific Body Analysis The Ellis Micro-Dynameter Mfd. by Ellis Research Laboratories, Inc. Chicago U.S.A."

LIBELED: 8-16-62, E. Dist. Mich.; 7-31-62, W. Dist. Wis.; 8-29-62 and 8-24-62, S. Dist. Calif.; 3-19-63, E. Dist. Tenn.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for

diagnosing disease; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use, and was not entitled to any exemption from that requirement.

DISPOSITION: Between 10-10-62 and 6-28-63. Default—3 devices delivered to the Food and Drug Administration; 18 devices destroyed.

7807. Research Model devices (4 seizure actions). (F.D.C. Nos. 47710, 47983, 48014, 48090. S. Nos. 34-286 T, 34-288 T, 51-825 T, 60-650/1 T.)

QUANTITY: 5 devices, at Duluth and Hibbing, Minn., Marquette, Mich., and Spokane, Wash.

SHIPPED: On various dates; from Cumberland, Wis., by Toftness Chiropractic Clinic, or Foundation for the Advancement of Chiropractic Research, Inc., by M. H. Cole, D.C., and by unknown shippers; and from Elkhart, Ind., by H. C. Lindahl.

LABEL IN PART: "Research Model" or "Neurolinometer Toftness System Cumberland Wisconsin" and/or "This instrument has no known analytical or therapeutic value" and/or "Limitation of Use: This instrument has no known therapeutic, diagnostic, or analytical value and shall not be used for any such purpose. Its use is strictly limited to personal research work by duly qualified practitioners in Chiropractic."

RESULTS OF INVESTIGATION: Examination indicated that the device was housed in a grey-colored box. One end of the box was a storage well containing a white powder used to dry the surface of the bakelite detector plate located in the upper right-hand corner of the box. The control panel contained two plugs for electrode outlets, a switch, fuse, and a variable dial graduated from 0 to 100. One electrode was a small metal disc probe attached to a wooden handle and the other electrode was a plastic-enclosed metal coil mounted on a metal gooseneck-type support. The device was used by placing the metal disc probe in contact with the supposedly affected part of the spine. Meanwhile, the operator rubbed his fingers across a metal plate attached to the device until a "pull" was felt on the fingers, while a numbered dial on the control panel was turned with the operator's other hand.

LIBELED: Between 7-11-62 and 9-10-62, Dist. Minn., W. Dist. Mich., and E. Dist. Wash.

CHARGE: 502(f) (1)—when shipped, the labeling of the article failed to bear adequate directions for use for the purpose for which it was intended, namely, for the diagnosis of disease in man, in that the article was worthless for use for such purpose, and adequate directions could not be given for the use of the article for such purpose.

DISPOSITION: Between 10-16-62 and 11-19-62. Default—destruction or delivery to the Food and Drug Administration.

7808. Mathison Electropsychometer. (F.D.C. No. 49107. S. No. 61-361 V.)

QUANTITY: 3 devices at Boerne, Tex.

SHIPPED: Prior to 5-23-63, from Los Angeles, Calif., by Arcon Manufacturing Co. (Mathison Manufacturing Co.).

LABEL IN PART: "Mathison Electropsychometer * * * Manufactured under license by Arcon Mfg. Co. * * * Los Angeles 7, California."

ACCOMPANYING LABELING: Leaflets bearing facsimiles of 2 different Food and Drug Administration Notices of Inspection (Form FD-482) and leaflets en-

titled "Complete operating instructions furnished with each Mathison Electropsychometer."

RESULTS OF INVESTIGATION: The device consisted of an electronic chassis containing meters, controls, power supply, and a vacuum bridge-type circuit and amplifier. Electrodes attached to the device supplied a small voltage to the hand electrode or probe and reacted to changes in the skin resistance or sweat gland activity.

LIBELED: 7-11-63, W. Dist. Tex.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective in diagnosing the causes of nervousness, emotional upsets, functional disorders, chronic fatigue, insomnia, distress, depression, worry, fears, illnesses, and hypertension; locating areas of impingement and inflammation; and locating and diagnosing other sub-optimum physical conditions; 502(a)—the use of reproductions of Food and Drug Administration Notices of Inspection and related explanations of the documents were false and misleading in that they suggested and implied that the article, its labeling, and its intended uses in medical practice had been sanctioned by the Food and Drug Administration; and 502(f) (1)—the labeling of the article failed to bear adequate directions for the intended uses of the article.

DISPOSITION: 12-11-63. Default—delivered to the Food and Drug Administration.

7809. Vibra-Matic mattress. (F.D.C. No. 48994. S. No. 79-204 V.)

QUANTITY: 1 mattress, and the following component parts: 25 vibrator motors, 25 timers, 50 flex-o-lator units, and 25 headgear (harnesses), at Denver, Colo., in possession of Certified Sleep Co.

SHIPPED: 4-1-63, from Wichita Falls, Tex., by Vibra-Matic Co.

LABEL IN PART: (Label on mattress) "The Vibra-Matic Health Aid Unit P.O. Box 1768 Wichita Falls, Texas," (tag) "Union Mattress & Pillow Co. Denver, Colorado," (motor) "The Vibra-Matic Health Aid Unit P.O. Box 1768 Wichita Falls, Texas," and (timer) "Home Unit Timer * * * Model 126 Spartus Timer * * * Herold Products Co., Inc. Chicago 12, Ill."

ACCOMPANYING LABELING: Leaflets entitled "Now is The Time * * * The Vibra-Matic * * * Health Aid Mattress * * * Relief Obtained—Recommended by Doctors"; and quantities of testimonial letters.

RESULTS OF INVESTIGATION: The component parts were shipped as described above and the mattress was manufactured in Denver, Colo., by the Union Mattress & Pillow Co.

The accompanying labeling was received by the dealer, from the Vibra-Matic Co. sales representatives, for the purpose of promoting sales of the article.

The literature and description of the device indicated that the article consisted of a mattress, electrical switch, motor, and metal frame which acted as support-housing for the motor, to which was attached a series of metal wires and cords which allegedly conveyed vibrations from the motor and housing, throughout the mattress.

LIBELED: 6-10-63, Dist. Colo.

CHARGE: 502(a)—when shipped and while held for sale, the name of the article and statements in its labeling were false and misleading in that they represented that the article was adequate and effective as a general health

aid, and in the treatment and prevention of nervous, emotional, and physical tensions, insomnia, tired muscles and joints, overstimulated muscles in active, growing youngsters, fatigue, hypertension, poor circulation, many chronic ailments, and pain caused by arthritis, rheumatism, backache, hemorrhoids, headaches and other medical conditions; and 502(f) (1)—while held for sale, the labeling failed to bear adequate directions for use of the article in the treatment and prevention of poor circulation, insomnia, nervous and emotional tensions, decreasing pain caused by arthritis, hemorrhoids, and headache, which were the conditions for which it was offered in a newspaper advertisement and in oral statements made by two salesmen of the Certified Sleep Co.

DISPOSITION: 11-1-63. Consent—claimed by Cecil Jeter, Wichita Falls, Tex., and released under bond for relabeling.

7810. Sleep-machine device and accessories. (F.D.C. No. 49344. S. No. 22-740 X.)

QUANTITY: 21 unlabeled, individually cased, *sleep-machine devices*, each case also containing an eye mask, neck pad, and electrical cord, 6 unlabeled eye-shades, and 1 unlabeled horsecollar, at Salt Lake City, Utah, in possession of Douglas Manusia, t/a Nap-A-Night.

SHIPPED: Between 4-22-63 and 5-30-63, from Minneapolis, Minn., by Johnston Hearing Aid & Electronics Co., Inc., t/a Johnston Sleep Machine Co.

ACCOMPANYING LABELING: Card in each of the device cases reading in part "Instructions * * * Johnston Sleep Machine Co. * * * Minneapolis"; article entitled "The Russians New Sleep Machine" by Dr. Cyril Solomon; form letter undated, on Johnston Hearing Aid & Electronics Co., Inc., letterhead, beginning "Electro-Rest is the American name for an instrument described in the January 13th issue of 'This Week' magazine"; letter dated April 12, 1963 from W. E. Johnston, reading in part "* * * The Sleep Machine is the modern electronic miracle you read about"; photocopy of a letter from Douglas Manusia ordering 10 "Electro-Rest" devices; form letter on Johnston Hearing Aid & Electronics Co., Inc., letterhead, reading in part "Electro-Rest Good For Tired Nerves"; letter dated April 24, 1963 from W. E. Johnston, beginning "The instruments you ordered have gone forward"; a form letter headed "Bulletin" on Johnston Sleep Machine Co. letterhead; letter dated May 3, 1963 on Johnston Hearing Aid & Electronics Co., Inc., letterhead to Douglas Manusia; letter dated May 6, 1963 from Douglas and Hazel Manusia; letter dated May 10, 1963 to Douglas Manusia; testimonial letter signed "Ed"; letter dated June 5, 1963 from W. E. Johnston; leaflets entitled "Nap-A-Night"; and copy of an advertisement in the June 2, 1963 issue of a local newspaper entitled "Can't Go To Sleep??? Nap-A-Night Sleep Inducing Machine Is The Answer."

RESULTS OF INVESTIGATION: The above leaflet entitled "Nap-A-Night" had been printed on order of the dealer and the above June 2, 1963 advertisement had been placed by the dealer.

Examination indicated that the article consisted of a small, hinged box with snap opener containing a battery-operated electrical circuit producing a pulsating, galvanic current which was applied through electrodes to the eyes or throat and the base of the skull. The current intensity was controlled by a single control knob on the face of the device.

LIBELED: 9-27-63, Dist. Utah.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling contained false and misleading representations that the articles were adequate and effective for relief of nervous tension; treatment for tired nerves, hypertension, insomnia, bursitis, herniated disc, and for other medical purposes; which statements were false and misleading, since the articles were not adequate and effective for such purposes; and 502(f) (1)—the labeling of the articles failed to bear adequate directions for use and they were not exempt from such requirement, since they had a potentiality for harmful effects and failed to comply with the exempting regulations.

DISPOSITION: 1-17-64. Default—delivered to the Food and Drug Administration.

DRUG FOR VETERINARY USE

7811. Phenothiazine powder and Val-A phenothiazine. (F.D.C. No. 49118. S. Nos. 12-402/3 X.)

QUANTITY: 1 150-lb. drum and 33 1-lb. ctns, of *phenothiazine powder*, and 1 100-lb. drum and 32 1-lb. ctns, of *Val-A phenothiazine*, at Chicago, Ill., in possession of Val-A Co.

SHIPPED: 8-17-62, from New York, N.Y.

LABEL IN PART: (Ctns.) "Val-A Phenothiazine (Powder) * * * Distributed by Val-A Company * * * Chicago 9, Ill." and "Val-A Phenothiazine Drench Mixture Active Ingredients: Phenothiazine 98.84% * * * Distributed by Val-A Company * * * Chicago 9, Ill."

RESULTS OF INVESTIGATION: Examination revealed that all of the articles had been shipped in bulk drums and had been repacked in part, by the dealer, into the 1-lb. packages.

LIBELED: 7-22-63, N. Dist. Ill.

CHARGE: 502(f) (1)—while held for sale, the labeling of the articles, namely, the drum and repack carton labels, failed to bear adequate directions for use of the articles in the treatment of worm and parasitic conditions in horses, calves, cattle, lambs, goats, and poultry, since, when used as directed, the articles would provide seriously excessive amounts of phenothiazine for the intended purposes; and 502(f) (2)—the labeling failed to bear adequate warnings against use of the articles in lactating dairy animals.

DISPOSITION: 1-24-64. Consent—destruction.

DRUG ACTIONABLE BECAUSE COLOR ADDITIVE DEEMED TO BE UNSAFE

7812. Coal-tar colors. (F.D.C. No. 48935. S. Nos. 66-201/2 V.)

QUANTITY: 35 1-lb. cans of green and 2 5-lb. cans of red, at Hato Rey, P.R., in possession of Granchel Medicine Co., Inc.

SHIPPED: 3-6-59 and 4-12-62, from New York, N.Y., by Fritzsche Bros., Inc.

LABEL IN PART: (Can) "Fritzsche Brothers, Inc., New York * * * 0323621398 * * * Color Inofensivo Certificado Verde Clorofila-Mescla De Colores Certificados D&C," and "Fritzsche Brothers, Inc. New York * * * 0323621398 * * * Color Inofensivo Certificado D&C Rojo #17."

RESULTS OF INVESTIGATION: Analysis showed that the *green chlorophyll color* consisted of a mixture of External D&C Orange No. 4, D&C Green No. 6, and D&C Yellow No. 11; and that the *red color* consisted of *D&C Red No. 17* as

stated on its label. Both articles were used to color cod liver oil for internal use.

The lot of *green chlorophyll color* was a commingled lot of two shipments.

LIBELED: 6-6-63, Dist. P.R.

CHARGE: *Green chlorophyll color*, 501(a)(4)(B)—when shipped and while held for sale, the article was a color additive and was unsafe within the meaning of 706, since it contained, among other ingredients, External D&C Orange No. 4, and the intended use of the color additive was not in conformity with a regulation or exemption in effect; 502(a)—the label statement "Harmless Certified Green Chlorophyll Color Mixture of Certified D&C Colors" was false and misleading; and 502(m)—the labeling of the article was not in conformity with the labeling requirements applicable to color additives for the purpose of coloring a drug, as contained in regulations, in that it did not bear the name of the color, External D&C Chlorophyll, the lot number identifying such color as being from a batch that had been certified, the percentage of pure dye in such color, and the statement "Not for use in coloring food, or in coloring any drug or cosmetic used internally or on the lips or any mucous membrane."

D&C Red No. 17, 502(m)—when shipped, the labeling of the article was not in conformity with the labeling requirements applicable to color additives for the purposes of coloring a drug, as contained in regulations, in that it failed to bear the lot number identifying the color as being from a batch that had been certified, the percentage of pure dye in such color, and the statement "Not for use in coloring food."

DISPOSITION: 8-16-63. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICES FOR HUMAN USE*

7813. Imitation Diuril tablets. (F.D.C. No. 47357. S. No. 16-856 R.)

INFORMATION FILED: 9-7-62, W. Dist. Ky., against Herman Michelson, t/a Dixie Drugs, Louisville, Ky.

ALLEGED VIOLATION: On 4-5-61, while a number of *imitation Diuril tablets* were being held for sale after shipment in interstate commerce, the defendant caused the article which was represented to be Diuril tablets, but was an imitation, to be offered for sale and sold to fill a prescription for Diuril, which act caused the article to be adulterated and misbranded.

CHARGE: 501(d)(2)—while held for sale, *imitation Diuril tablets* were substituted for Diuril tablets; 502(i)(2)—the article was an imitation of another drug, namely, Diuril; and 502(i)(3)—the article was offered for sale under the name of another drug, namely, Diuril.

PLEA: Nolo contendere.

DISPOSITION: 11-5-62. \$200 fine.

7814. Reserpine powder and tablets. (F.D.C. No. 49509. S. Nos. 41-568/9 X.)

QUANTITY: 1 14-kilo drum of *reserpine powder*; 95 1,000-tablet btls. and 6 10-tablet btls. of *reserpine tablets*, at New York, N.Y., in possession of Park Drug Co.

*See also Nos. 7781, 7789, 7792, 7799.

SHIPPED: 6-21-63, from South Hackensack, N.J., by Stanley Blackman Laboratories, Inc.

LABEL IN PART: (Drum) "Stanley Blackman Labs., Inc., So. Hackensack, New Jersey * * * To Park Drug Company, Inc. * * * 25 Kilos Reserpine 1% trituration in lactose * * * Caution"; and (btl.) "Reserpine Tablets U.S.P. 0.25 mg. Caution * * * Park Laboratories, New York, N.Y."

RESULTS OF INVESTIGATION: All of the articles had been shipped in bulk as powder; the dealer had tableted the powder and repacked the tablets into bottles.

Analysis showed that the bulk powder contained 0.77 percent of reserpine alkaloids and that the tablets contained 78 percent of the labeled amount of reserpine alkaloids.

LIBELED: On or about 11-7-63, S. Dist. N.Y.

CHARGE: *Reserpine powder*, 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Reserpine 1%" was false and misleading as applied to a product containing less than the declared amount of reserpine.

Reserpine tablets, 501(b)—while held for sale, the article purported to be and was represented as a drug, "*Reserpine Tablets*," the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from and its quality fell below the standard set forth in such compendium; and 502(a)—the label statement "Reserpine tablets U.S.P." was false and misleading as applied to a product that did not conform to the United States Pharmacopeia standards.

DISPOSITION: 12-30-63. Default—destruction.

7815. **Jettup B Complex with B₁₂ tablets.** (F.D.C. No. 48942. S. No. 20-896 V.)

QUANTITY: 1 drum containing 9,400 tablets and approximately 86,100 tablets in 100-tablet btls., at Dallas, Tex.

SHIPPED: 9-24-59, from Long Island City, N.Y.

LABEL IN PART: (Btl.) "Fast Acting Jettup B Complex with B₁₂ Each tablet contains Thiamine Hydrochloride (B₁) 50 mg. * * * Pyridoxine Hydrochloride (B₆) 1 mg. * * * Southern Chemical Foundation, Inc., * * * Dallas, Texas * * * Each Tablet Supplies * * * Dosage: Since the body stores of Vitamin B₁ are never large and may be reduced by overindulgence, improper diet or stress, suggested dosage is two tablets with water daily after any meal for three weeks; thereafter, one tablet daily, or as directed by physician."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 60 percent of the declared amount of thiamine hydrochloride and approximately 50 percent of the declared amount of pyridoxine hydrochloride.

The article, after arrival at Dallas, Tex., was repacked into the above-described bottles by Goodrich-Wright, Inc., for the Southern Chemical Foundation.

LIBELED: On or about 5-21-63, N. Dist. Tex.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; 502(a)—the statement on the drum label "Each Tablet * * * contains * * * Thiamine Hydrochloride 50 mg. Pyridoxine HCl 1 mg." and the statement on the bottle label "Each tablet contains Thiamine Hydrochloride (B₁) 50 mg. * * * Pyridoxine Hydrochloride (B₆) 1 mg." were false and misleading; and 502(a)—the name of the article,

"Jettup," and statements in its labeling (repack label), represented and suggested that the article was adequate and effective for the treatment of nervous tension, uncontrolled movements of the hands and legs, irritability, fast pulse, fatigue, loss of appetite, inability to sleep, swelling of the face and ankles, decrease in mental and physical efficiency, blurred vision, irritation of the eyes, corners of the mouth and nostrils, and swelling, redness and soreness of the tongue; and that the article was unusually fast acting in the treatment of disease; which name and statements were false and misleading, since the article was not adequate and effective for such purposes, and since the statements were otherwise contrary to fact.

DISPOSITION: 8-5-63. Default—destruction.

7816. Nutri-Bio food supplement. (F.D.C. No. 49082. S. Nos. 28-183 V, 28-185 V.)

QUANTITY: 11 cases, each containing 24 pkgs., each pkg. containing 829 mineral tablets and 364 vitamin tablets, and 15 cases, each containing 12 pkgs., each pkg. containing 42 vitamin tablets and 84 mineral tablets, at Omaha, Nebr.

SHIPPED: Between 2-7-63 and 2-13-63, from El Segundo, Calif., by Nutri-Bio Corp.

LABEL IN PART: (Pkg.) "Nutri-Bio dietary food supplement * * * 2 Vitamin Tablets and 4 Mineral Tablets Daily will supply: Vitamin A * * * 8000 USP Units * * * Vitamin C * * * 60 Mg. * * * Vitamin B-12 Activity (Cobalamin) 5 mcg. * * * Formulated for and Distributed by Nutri-Bio Corporation Beverly Hills, Calif."

ACCOMPANYING LABELING: Leaflets entitled "The Nutri-Bio Program For Better Living" and "Do You Know."

RESULTS OF INVESTIGATION: Analysis showed that the 11-case lot contained approximately 70 percent of the declared amount of vitamin B₁₂ and approximately 75 percent of the declared amount of vitamin A; and the 15-case lot contained approximately 75 percent of the declared amount of vitamin C.

LIBELED: 6-18-63, Dist. Nebr.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it was represented to possess since the constituents, vitamin B₁₂, vitamin A, and vitamin C, were omitted in part; 502(a)—the label statement "2 Vitamin Tablets and 4 Mineral Tablets Daily will supply: Vitamin A * * * 8000 USP Units * * * Vitamin C * * * 60 Mg. * * * Vitamin B-12 Activity (Cobalamin) 5 mcg." was false and misleading as applied to a product containing less than the declared amounts of these ingredients; 502(a)—when shipped, the labels of the article contained false and misleading representations that the article was of significant value for special dietary supplementation and therapeutic use by reason of the presence therein of unsaturated fatty acids, inositol, para-aminobenzoic acid, rutin, biotin, bioflavonoid complex, hesperidin complex, choline, alfalfa juice and powder concentrate, copper, manganese, magnesium, potassium, sulfur, chlorine, and montmorillonite (wonder clay); and because the ingredients of the article were of natural or organic origin; and 502(a)—the accompanying labeling contained false and misleading representations that the article was adequate and effective to promote mental and physical health, happiness, sociability, enthusiasm, liveliness, vigor, alertness, and awareness.

DISPOSITION: 8-20-63. Default—destruction.

7817. C-112 Wetting Solution (2 seizure actions). (F.D.C. Nos. 47515, 47566. S. Nos. 61-074 T; 26-283/4 T.)

QUANTITY: 20 cases, each containing 12 ctns. of 16 2-oz. btls. each, plus 17 2-oz. btls., and 19 cases, each containing 50 5-cc. btls., at Hazel Park, Mich.

SHIPPED: 10-5-61, from Wauconda, Ill., by Micon Laboratories, Inc.

LABEL IN PART: (Btl.) "2 Fl. Oz. Lot No. 20001 C-112 Wetting Solution A Sterile Wetting Solution for Cleaning, Lubricating and Wetting Contact Lenses. Distributors Wagner Products Co. * * * Hazel Park, Michigan Directions * * * Sterile" and (btl.) "5 cc. Lot No. 20001 C-112 Wetting Solution Directions: * * * Wagner Products Co. Hazel Park, Michigan."

LIBELED: 5-31-62 and 5-2-62, E. Dist. Mich.

CHARGE: 501(c)—when shipped, the purity and quality of the article fell below that which it purported and was represented to possess, since all lots of the article were represented to be suitable for wetting contact lenses, and one lot was represented to be sterile, whereas the article was not suitable for wetting contact lenses and was not sterile, since it was contaminated with viable micro-organisms; 502(a)—the label statement "Sterile" was false and misleading; and 502(e) (2)—the label of a portion of the article failed to bear the common or usual name of each active ingredient.

DISPOSITION: 3-5-63. Consent—destruction.

7818. Rubber prophylactics. (F.D.C. No. 49726. S. No. 14-293 X.)

QUANTITY: 82 ctns., each containing 72 2-unit pkgs., at Chicago, Ill.

SHIPPED: 11-11-63, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Royal Marquis Prophylactics * * * Distributed by Royal Products Chicago, Illinois * * * Sold for the prevention of disease only."

RESULTS OF INVESTIGATION: Examination of 50 prophylactics showed that 4 percent were defective in that they contained holes.

LIBELED: 1-16-64, N. Dist. Ill.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "Sold for the prevention of disease only" was false and misleading.

DISPOSITION: 2-26-64. Default—destruction.

7819. Rubber prophylactics. (F.D.C. No. 49437. S. No. 27-789 X.)

QUANTITY: 8 cases, each case containing 25 boxes, each box containing 72 2-unit pkgs., at North Kansas City, Mo.

SHIPPED: 10-1-63, from Durham, N.C., by Barnetts, Inc.

LABEL IN PART: (Pkg.) "KENT SOLD FOR THE PREVENTION OF DISEASE ONLY—Manufactured for Allied Latex Sales Co., Newark, New Jersey."

RESULTS OF INVESTIGATION: Examination showed that 1.3 percent of the article examined contained holes.

LIBELED: On or about 11-14-63, W. Dist. Mo.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statement "SOLD FOR THE PREVENTION OF DISEASE ONLY" was false and misleading.

DISPOSITION: 3-10-64. Default—destruction.

7820. Rubber prophylactics. (F.D.C. No. 49330. S. No. 18-373 X.)

QUANTITY: 14 ctns., each containing 12 12-unit pkgs., and 20 ctns., each containing 4 36-unit pkgs., at Dallas, Tex.

SHIPPED: 7-10-63, from Cleveland, Ohio, by Schaeffer Products Co., Inc.

LABEL IN PART: (Pkg.) "Gensco Prophylactics Packed by Schaeffer Products Co. Cleveland, Ohio * * * Sold only to prevent disease," (ctn.) "Gensco 12's Rolled Prophylactics * * * Sold for prevention of disease only Schaeffer Products Co., Inc. Cleveland, Ohio," (pkg.) "Gensco Rolled Prophylactics * * * Assists in protecting health through the prevention of venereal disease and the reinfection of the female with trichomonas Packed by Schaeffer Products Co., Inc. Cleveland, Ohio," and (ctn.) "Gensco 36's Rolled Prophylactics * * * Assists in protecting health through the prevention of venereal disease and the reinfection of the female with trichomonas. Schaeffer Products Co., Inc. Cleveland, Ohio."

RESULTS OF INVESTIGATION: Examination showed that 0.83 percent of the article examined contained holes.

LIBELED: 10-10-63, N. Dist. Tex.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it was purported to possess; and 502(a)—the label statements "Sold only to prevent disease," "Sold for prevention of disease only," and "Assists in protecting health through the prevention of venereal disease and the reinfection of the female with trichomonas" were false and misleading.

DISPOSITION: 2-27-64. Default—destruction.

DRUG FOR VETERINARY USE*

7821. Medicated Super Egg Atoms feed. (F.D.C. No. 49217. S. No. 29-822 X.)

QUANTITY: 39 50-lb. bags at Omaha, Nebr.

SHIPPED: Between 5-3-63 and 6-4-63, from Kansas City, Mo., by Professional Feeds, Beacon Div. of Textron, Inc.

LABEL IN PART: (Bag) "Professional Brand Medicated super egg atoms Beacon Division of Textron, Inc. * * * Kansas City 16, Mo. * * * Active Drug Ingredient Furazolidone 0.011% (100 grams per ton)."

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than the declared amount of furazolidone. The feeding directions on the label for the prevention of blackhead and paracolon and for control of coccidiosis in chickens were inconspicuous due to the smallness of the type and blurring.

LIBELED: 8-7-63, Dist. Nebr.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; 502(a)—the label statement "Furazolidone 0.011% (100 grams per ton)" was false and misleading as applied to a product containing less than the declared amount of this ingredient; 502(a)—the label statement "The high level of antibiotics and vitamins in Medicated Super Atoms" represented that the article contained a high level of antibiotics, which statement was false and misleading, since it was contrary to fact; and 502(c)—the information required to appear on the label under section 502(f) (1), namely, the directions for use, was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or

*See also No. 7782.

devices in the labeling) as to render it likely to be read by the ordinary individual under customary conditions of purchase and use.

DISPOSITION: 9-19-63. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS AND DEVICES FOR HUMAN USE*

7822. *Corticotropin gel injection and vitamin B₁₂ injection.* (F.D.C. No. 47335. S. Nos. 25-385 R, 72-626 R.)

INDICTMENT RETURNED: 6-18-63, Dist. Ariz., against Western Serum Co., a partnership, Phoenix, Ariz., and Edward J. Prochaska, Jr., and Wallace F. Schmidt, partners.

ALLEGED VIOLATIONS: On 3-22-61, the individuals caused, and the partnership with intent to defraud and mislead caused, to be shipped, a number of misbranded vials of *corticotropin gel injection* from Phoenix, Ariz., to Las Vegas, Nev.

Between 8-1-60 and 12-23-60, while a number of 10-cc. vials of 500 micrograms per cubic centimeter of vitamin B₁₂ were being held for sale after shipment in interstate commerce, the individuals caused, and the partnership with intent to defraud and mislead caused, to be removed, the original labels which had been affixed to the vials of the drug when shipped in interstate commerce, and the vials of the drug to be relabeled, which acts resulted in the drug being misbranded.

LABEL IN PART: (Vials) "Purified Corticotropin Gel Repository Corticotropin Injection U.S.P. Each cc contains 80 U.S.P. Corticotropin Units" and "10 cc Vial Vitamin B-12 1,000 mcgm./cc Crystalline U.S.P. Intravenous Intramuscular."

CHARGE: *Corticotropin gel injection*, 502(a)—when shipped, the article's label statement "Repository Corticotropin Injection U.S.P. Each cc contains 80 U.S.P. Corticotropin" was false and misleading since each cubic centimeter of the article contained substantially less than 80 U.S.P. corticotropin units.

Vitamin B₁₂ injection, 502(a)—while held for sale, the article's label statement "Vitamin B-12 1,000 mcgm./cc * * * U.S.P. Intravenous Intramuscular" was false and misleading since the article contained substantially less than 1,000 micrograms of vitamin B₁₂ per cubic centimeter.

PLEA: Guilty.

DISPOSITION: 12-9-63. Partnership—imposition of sentence suspended for 5 years; each individual—suspended sentence of one year in jail, probation for 5 years, and \$1,000 fine.

7823. *Amitone tablets.* (F.D.C. No. 47696. S. No. 64-875 T.)

QUANTITY: 87 boxes, each containing 36 individually ctnd. btl., at Los Angeles, Calif.

SHIPPED: 10-28-61, in bulk drums, from Cleveland, Ohio.

LABEL IN PART: (Btl.) "The Antacid With Glycine Amitone 100 Tablets Relieves Acid Indigestion in seconds, for hours! Norex Laboratories, Inc., NYC Directions: Two tablets: Allow to melt in mouth, chew, or swallow

*See also Nos. 7781, 7784, 7787, 7789-7795, 7798-7802, 7805, 7806, 7808-7810, 7812, 7814-7820.

with water if preferred . . . Repeat as needed. Active ingredients: Glycine and Calcium Carbonate * * * Most effective in relieving indigestion, sour stomach, heartburn, due to excess acidity."

ACCOMPANYING LABELING: (Carton insert) "Amitone the physician's formula . . . antacid . . . containing a special ingredient . . . GLYCINE with milk-like buffering action."

RESULTS OF INVESTIGATION: The article was manufactured in Cleveland, Ohio, for Norex Laboratories, Inc., New York N.Y., and after its shipment, as described above, was repacked at Los Angeles, Calif., into bottles and cartons. The bottles, cartons, labels, and package inserts were supplied by Norex Laboratories, Inc.

LIBELED: 7-3-60, S. Dist. Calif.; libel amended 4-10-63, E. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the labeling of the article contained statements which represented and suggested that two tablets had the acid neutralizing power of a full pint of milk; that if taken as directed, the article was most effective in relieving indigestion, sour stomach, gas, and heartburn due to excess acid; that the article relieved acid indigestion in seconds, for hours; that it contained a special ingredient, glycine, with a milk-like buffering action; and other statements which represented and suggested that the article was an adequate and effective treatment for all conditions, such as peptic ulcers, that exhibit symptoms of hyperacidity; which statements were false and misleading, since the article was not adequate and effective for such purposes, and since hyperacidic conditions, other than those due to overindulgence in food and drink, are not amenable to self-diagnosis and treatment by the laity.

DISPOSITION: Pursuant to stipulation by the Government and the claimant, Norex Laboratories, Inc., an order was entered on 8-13-62 directing the transfer of the case to the Eastern District of New York. On 5-7-63, the claimant filed an answer denying that the article was misbranded. Written interrogatories were thereafter served upon the claimant by the Government and were subsequently answered by the claimant. On 4-1-64, the claimant having withdrawn its claim and answer, the court entered a default decree providing for condemnation of the article and its delivery to a public institution, or its destruction.

7824. **Dextra Sugar.** (F.D.C. No. 45698. S. No. 14-996 R.)

QUANTITY: 224 cases of 12 3-lb. bags each, at Hamilton, Ohio.

SHIPPED: 2-2-61, from Delray Beach, Fla., by Sugarlogics World Corp.

LABEL IN PART: (Bag) "New! Dextra Sugar Fortified with Vitamins and Minerals 27 Health Building Nutrients White—Granulated Packed with Health Power for the Entire Family! * * * Dextra Gives You These Nutritional Benefits! * * * A Product of The Sugarlogics World Corporation Manufactured and Distributed in Florida by The Sugarlogics Southern Corporation, Delray Beach, Florida" and (tag) "Dextra Sugar Saves You Money On Essential Vitamins and Minerals! Gives You Abundant Health Benefits As You Eat!"

LIBELED: 4-6-61, S. Dist. Ohio.

CHARGE: 502(a)—when shipped, the label contained false and misleading representations that the article was adequate and effective to produce and maintain health; maintain energy and vitality; build strong, beautiful teeth;

prevent overweight; and prevent and control excessive fat deposits in the blood vessels, muscles, and vital organs.

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 5-8-61. Default—delivered to a charitable institution.

7825. Cal-Re-Low dietary supplement. (F.D.C. No. 46241. S. Nos. 88-665/6 R.)

QUANTITY: 16 14-oz. jars and 18 7-oz. jars, at Kansas City, Mo.

SHIPPED: 5-18-61, from Minneapolis, Minn., by Pavo Co., Inc.

LABEL IN PART: (14-oz. jar) "Pavo High Protein Cal-Re-Low Weight Control Supplement 'A Meal-In-Itself' 65% Complete Protein 30 Vitamins—Minerals 7 Basic Nutrients Black Cherry Flavor * * * Packed and Distributed by The Pavo Co., Inc., Minneapolis, Minnesota * * * Directions * * * As a Dietary Supplement 3 well-rounded tablespoonsful (1½ oz.) 'Cal-Re-Low' supplies * * * Folic Acid .6 Mg." and (7-oz. jar) "Pavo 65% Complete Protein Cal-Re-Low Weight Control Aid 'A Meal-In-Itself' 17 Vitamins—13 Minerals 7 Basic Nutrients Unflavored Packed and Distributed by The Pavo Co., Inc. Minneapolis, Minnesota * * * Directions * * * As A Dietary Supplement 3 well-rounded tablespoonsful (1½ oz.) 'Cal-Re-Low' supplies * * * Folic Acid .6 Mg."

ACCOMPANYING LABELING: Pamphlet entitled "Overweight? Underweight? Cal-Re-Low a dual-purpose food may be Your Answer."

LIBELED: On or about 8-7-61, W. Dist. Mo.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for and preventive of overweight and underweight conditions, nervousness, fatigue, tension, sleeplessness, and irritability; and to build the body; promote strength, energy, and health; normalize body conditions; and to satisfy the appetite.

The article was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 11-29-61. Default—destruction.

7826. Various vitamin, mineral, lecithin, and oil products. (F.D.C. No. 46577. S. Nos. 39-281 T, 39-283/6 T, 40-484/5 T.)

QUANTITY: 3 bulk ctns. of *carotene and vitamin E capsules*; 6 100-capsule btl. of *A-E Plus capsules*; 6 bulk ctns. of *25,000-unit vitamin A capsules*; 17 ctns., each containing 24 100-capsule btl., 2 ctns., each containing 24 500-capsule btl., and 8 100-capsule btl. of *Speed-A-Vite capsules*; 56 ctns., each containing 24 100-capsule btl., and 9 ctns., each containing 24 500-capsule btl., of *26,000-unit vitamin A capsules*; 16 bulk ctns. of *lecithin-safflower oil capsules*; 20 100-capsule btl. of *Saftinol capsules*; 41 ctns., each containing 24 100-capsule btl., and 3 ctns., each containing 24 500-capsule btl., of *A-D Vitamins*; 12 ctns., each containing 24 500-capsule btl., of *halibut liver oil*; 18 ctns., each containing 24 100-capsule btl., 10 ctns., each containing 12 500-capsule btl., of *soybean lecithin capsules*, at Valley Stream, N.Y., in possession of Barth Levitt Products.

SHIPPED: Between 2-19-61 and 10-23-61, from Cleveland, Ohio; Detroit, Mich.; and Newark, N.J.

LABELS IN PART: (Ctn.) "Special A E Capsules 7½ mg. * * * Formula contains * * * per capsule Carotene (Provitamin A) 5000 Units, Wheat Germ Oil 2 mg., Vitamine E (* * *) 20 IU, Soya Lecithin Bleached 4"; (btl.) "A-E Plus An all-natural vegetable formula with Pro Vitamin A (carotene)—Vitamin E—Wheat Germ Oil—Soybean Lecithin * * * Distributed by Barth Levitt Products, Lynbrook, N.Y."; (ctn.) "Dispersible Vitamin A Natural (Speed-A-Vite) * * * Ingredients in each capsule: Vitamin A Natural 25,000 USP Units (From Vanco Vitamin A Dry, Food, Grade)"; (btl.) "Natural Barth's Speed-A-Vite Capsules 25,000 USP Units of Natural Vitamin A * * * Distributed by Barth Levitt Products, Valley Stream, N.Y."; (btl.) "Barth's Vitamin A Natural 26,000 USP Units * * * Contents * * * Distributed by Barth Levitt Products Valley Stream, N.Y."; (ctn.) "Special Capsules Ingredients in each capsule: * * * Lecithin-Soy 200 mg. Vitamin E (* * *) 10 Int'l. Units Vitamin B-12 Activity * * * 1 mcg. Inositol 50 mg. Safflower Oil 510.542 mg."; (btl.) "Natural-Organic Saffinol Capsules * * * Distributed by Barth Levitt Products, Lynbrook, N.Y."; (btl.) "Barth's A-D Vitamins Natural—High Potency Useful in the prevention of vitamin A & D deficiencies Each capsule contains * * * Contents * * * Distributed by Barth Levitt Products Valley Stream, N.Y."; (btl.) "Halibut Liver Oil Natural * * * Vitamin A (Natural) 5000 USP units, Vitamin D (Natural) 85 USP units, * * * Distributed by Barth Levitt Products Valley Stream, N.Y."; (btl.) "8 Grains Barth's Soy Bean Lecithin * * * Each capsule contains 8 grains of Soybean Lecithin * * * Distributed by Barth Levitt Products Valley Stream, N.Y."

ACCOMPANYING LABELING: Catalogs entitled "Barth's of Long Island Guide to Health Autumn [or "Mid-Summer"] Issue"; and repack labels for *A-E Plus capsules*, *Speed-A-Vite capsules*, and *Saffinol capsules*.

RESULTS OF INVESTIGATION: The catalogs had been printed on order of the dealer and were used in promoting sales of the articles. The bulk articles, namely, *carotene and vitamin E capsules*, *25,000-unit vitamin A capsules*, and *lecithin-safflower oil capsules*, had been repacked in part by the dealer as *A-E Plus capsules*, *Speed-A-Vite capsules*, and *Saffinol capsules*, respectively.

LIBELED: 10-23-61, E. Dist. N.Y.

CHARGE: *A-E Plus (carotene and vitamin E) capsules* as repacked and in bulk: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was adequate and effective for the treatment and prevention of infection; infection of mucous membranes of the eyes, nose, mouth and throat; a wide range of ills; to protect against adverse changes in the body; improve nutrition and health; promote growth; promote healthy eyes and skin; that the wheat germ oil and lecithin in the article would promote significantly the absorption of vitamin A and vitamin E; and that the lecithin in the article would promote fat digestion and fat transport in the body, particularly for people over forty.

Speed-A-Vite (25,000-unit vitamin A) capsules as repacked and in bulk: 502(a)—while held for sale, the labeling and the name of the article contained false and misleading representations and suggestions that the article was adequate and effective for the treatment and prevention of infection of the mucous membranes of the eyes, nose, mouth and throat; to prevent infection; promote growth and healthy eyes and skin; and that the article was of unusual benefit, by reason of the presence therein of acacia, to absorb vitamin A of the article into the bloodstream more rapidly and to a greater extent.

26,000-unit vitamin A capsules: 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective for the treatment and prevention of infections; infection of the mucous membranes of the eyes, nose, mouth and throat; and to promote growth and healthy eyes and skin.

Saftinol (lecithin-safflower oil) capsules as repacked and in bulk: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was adequate and effective to dissolve fat; promote fat transporting in the body; to build the blood; and to promote all functions of the body.

A-D Vitamin capsules and halibut liver oil capsules: 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the articles were adequate and effective for the treatment of mucous membranes of the eyes, nose, mouth and throat; poor bone and tooth development in children; muscle weakness; tooth decay; and bone disorders; to promote growth, healthy eyes and skin; and that the articles would regulate the use of calcium and phosphorus.

Soybean lecithin capsules: 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective to promote fat digestion and fat transport in the body, particularly for people over forty.

The libel alleged also that the *soybean lecithin capsules* and another article known as Sea Spray sea salt, as repacked and in bulk, were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: On 1-22-62, Barth-Levitt Products, Inc., having claimed the articles, a consent decree of condemnation permitting relabeling was filed. On 3-29-63, the claimant having represented to the court that it was impractical to bring the articles into compliance with the law and consented that the articles be destroyed, an order of destruction was entered.

7827. Vitamin capsules. (F.D.C. No. 49918. S. Nos. 050-348 A, 050-355 A.)

QUANTITY: 3 ctns. containing 45,000 capsules and 31 360-tablet btl. of *vitamin capsules*, and 2 drums, each containing 10,000 capsules, 48 270-capsule btl., and 7 180-capsule btl., of *food supplement*, at Battle Creek, Mich., in possession of Robinson Foods, Inc.

SHIPPED: 9-4-63 and 2-19-64, from Newark, N.J.

LABEL IN PART: (Btl.) "Robinson's Vitamin Capsules * * * Sole Distributor Robinson Foods, Inc. Battle Creek, Mich. Directions As a dietary supplement * * * Source of Ingredients Vitamin A Natural Ester, Vitamin D irradiated ergosterol" and "Robinson's Food Supplement Vitamin D With Soy Bean Lecithin Distributors Robinson Foods, Inc. Battle Creek, Mich."

ACCOMPANYING LABELING: Booklets entitled "Text of Talk by Harold O. Robinson President Robinson Foods, Inc."; business reply cards, reading "The Science of Nutrition"; reprints entitled "20 Thursday, Sept. 14, 61 Detroit Free Press Sylvia Porter 9 in 10 Leaders in U.S. Business"; and leaflets entitled "All diseases are caused by chemicals . . . , Dr. Tom Douglas Spies * * * Anyone who speaks up against food adulteration . . . Dr. Edward J. Ryan" and "Do You Need Lecithin? (Reprint, 'Prevention,' Dec., 1954)."

RESULTS OF INVESTIGATION: The articles were shipped in bulk, and repacked and labeled by the dealer. The dealer also prepared the accompanying labeling which was used to promote sales of the article.

LIBELED: 3-12-64, W. Dist. Mich.

CHARGE: *Vitamin capsules*, 502(a)—while held for sale, the labeling of the article (bulk and repack) contained false and misleading representations that the article was useful to people in preventing heart attacks, colitis, ulcers, fatigue, hemorrhoids, varicose veins, cataracts, and many other diseases; and that practically everyone in this country is suffering from, or in danger of suffering from, a dietary deficiency of vitamins and minerals.

Food supplement capsules, 502(a)—while held for sale, the labeling of the article (bulk and repack) contained false and misleading representations that lecithin was adequate and effective as a preventive, treatment, and cure for hypercholesterolemia, atherosclerosis, coronary thrombosis, gallstones, diabetes, keratosis, eczema, scleroderma, senile atrophy of the skin, seborrheas, and acne; and that use of the article would overcome the deleterious effects stated to be due to refined and processed foods.

DISPOSITION: 3-24-64. Default—destruction.

7728. Vitamin capsules. (F.D.C. No. 47396. S. Nos. 51-152/3 T.)

QUANTITY: 4 cases, each containing 20,000 capsules, 3,842 110-capsule btl., and 346 220-capsule btl., of *Cy-B-7 Multivitamin capsules*; and 17 cases, each containing 18,000 capsules, and 32 220-capsules btl., of *Formula 9 vitamin capsules*, at Monmouth, Oreg., in possession of Basic Remedies, Inc.

SHIPPED: Between 10-31-61 and 12-6-61, from Newark, N.J., and South Pasadena, Calif.

LABEL IN PART: (Btl.) "CY-B-7 Vitamin Capsules * * * Directions As a Dietary supplement * * * Distributed by Basic Remedies, Inc., Monmouth, Oregon" and "B.R.'s Formula 9 Vitamin Capsules * * * Directions as a dietary supplement * * * Distributed by Basic Remedies, Inc., Monmouth, Oregon."

ACCOMPANYING LABELING: Booklets entitled "Better Hair thru Body Chemistry"; inserts entitled "Slow Delivery?" "This is to order Basic Remedies, Inc.," and "Announcement of the new capsule Cy-B-7"; order blanks entitled "Dear Sir: Send me at once" and "Dear Sir: Under the comprehensive guarantee * * *"; leaflets entitled "Yes, of course. Take your Vitamins in the way that stimulates HAIR GROWTH"; envelopes entitled "Postage will be paid by—Basic Remedies Inc." and "B.R. 283 E. Main Street, Monmouth, Oregon"; folders entitled "Reports from the Scientific Journals Regarding Hair Growth" and "Introducing * * * B.R.'s Formula 9"; order card entitled "Dear Sir: Send me * * * selling kit"; letters entitled "Hair Growth Report: * * *," "A few days ago * * *," and "Thank you—for your interest"; placard entitled "Take your Vitamins in the way that stimulates Hair Growth"; and additional repack labels.

RESULTS OF INVESTIGATION: The articles were shipped in bulk and were repacked and labeled by the dealer, who also prepared the accompanying labeling which was used in promoting sales of the articles.

LIBELED: 3-20-62, Dist. Oreg.

CHARGE: 502(a)—while held for sale, the labeling accompanying the articles contained false and misleading representations that the articles were adequate and effective to promote new hair growth on bald or thin areas; to grow hair faster; to conserve hair that becomes too fine; to prevent falling hair; to promote waviness of hair; to promote a feeling of well-being, livelier health, and energy; and to prevent dandruff; and 502(a)—the labeling contained

statements that the articles had been approved by the United States Post Office Department, which were false and misleading.

DISPOSITION: The articles were claimed by Basic Remedies, Inc. On 5-17-63, a consent decree of condemnation was entered in which the claimant admitted that the labeling of the article contained statements that the United States Post Office had examined and approved the articles for shipment through the mails, and statements that the formula, products, labels, and advertising had been accepted for interstate commerce through the mails; and further admitted that such statements were misleading in that the proceedings on which they were based were proceedings in which the actual determination of the Post Office Department was that the claimant was not engaged in fraudulent use of the mails in violation of the law pertaining thereto; and the claimant further admitted that the articles were misbranded to that extent. The claimant denied the other allegations in the libel. The articles were destroyed, with the exception of empty "Postage will be paid by . . ." envelopes which were returned to the claimant.

7829. Regimen tablets (13 seizure actions). (F.D.C. Nos. 49661, 49709, 49711, 49727, 49728, 49731, 49732, 49735, 49747, 49749, 49750, 49752, 49767. S. Nos. 12-512 X; 4-935 X; 013-461/2 A; 054-101/2 A; 055-301/2 A; 006-802/3 A; 24-981 A; 24-381 A, 24-421 A, 24-982/5 A; 006-862/3 A; 2-381 A; 078-841 A; 006-503 A; 24-824 A.)

QUANTITY: 57 cases, each containing 36 156-tablet boxes, 93 156-tablet boxes, 15 cases, each containing 72 78-tablet boxes, and 1,032 78-tablet boxes, at Chicago, Ill.; 1,728 78-tablet boxes, at Baltimore, Md.; 809 78-tablet boxes and 62 156-tablet boxes, at Providence, R.I.; 692 78-tablet boxes and 186 156-tablet boxes, at Kansas City, Mo.; 33 156-tablet boxes and 74 78-tablet boxes, at Kansas City, Mo.; 31 156-tablet boxes and 59 78-tablet boxes, at Richmond, Va.; 615 78-tablet boxes and 186 156-tablet boxes, at Melrose Park, Ill.; 108 78-tablet boxes, at Skokie, Ill., 503 78-tablet boxes and 142 156-tablet boxes, at Chicago, Ill., 283 78-tablet boxes and 53 156-tablet boxes, at Chicago, Ill., 422 78-tablet boxes and 444 156-tablet boxes, at Chicago, Ill., 360 78-tablet boxes and 38 156-tablet boxes, at Oak Lawn, Ill., and 199 78-tablet boxes and 18 156-tablet boxes, at Chicago, Ill.; 33 78-tablet boxes, and 85 156-tablet boxes, at Baltimore, Md.; 281 78-tablet boxes, at Jacksonville, Fla.; 24 156-tablet boxes, at Newark, N.J.; 221 78-tablet boxes and 139 156-tablet boxes, at Alexandria, Va.; and 81 78-tablet boxes and 68 156-tablet boxes, at Chicago, Ill.

SHIPPED: Between 12-28-62 and 12-16-63, from Long Island City, N.Y., and New York City, N.Y., by Drug Research Corp.

LABEL IN PART: (Box) "For Excess Weight Reduction by Appetite Control Regimen-Tablets * * * contain: (In Green tablets) Vitamin D (irradiated yeast, B₁, B₂, B₆ and C. Niacinamide, Calcium Pantothenate, Diastase of Malt, and Benzocaine. (In Yellow tablets) Phenyl-Propanolamine Hydrochloride, Caffeine Alkaloid Anhydrous, Iron (Ferrous Sulfate), Potassium Iodide, Copper (Cupric) Sulfate, and Manganese Sulfate. (In Pink tablets) Ammonium Chloride * * * Distributor: Drug Research Corporation, New York, N.Y."

ACCOMPANYING LABELING: Circular reading in part "Reduce with the Regimen Plan: A New Dietary Combination to Satisfy Hunger Remove Excess Water Control and Inhibit Appetite Drug Research Corp. New York, New York * * * As Long as you have weight to lose follow the Regimen Plan and each week you will notice a weight loss."

LIBELED: 1-6-64, N. Dist. Ill.; 1-7-64, Dist. Md.; 1-15-64, Dist. R.I.; 1-16-64, W. Dist. Mo. (2 actions); 1-20-64, E. Dist. Va.; 1-16-64, N. Dist. Ill.; 1-17-64, N. Dist. Ill.; on or about 1-29-64, Dist. Md.; 2-13-64, M. Dist. Fla.; on or about 2-6-64, Dist. N.J.; 1-28-64, E. Dist. Va.; 2-3-64, N. Dist. Ill.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for weight reduction and control by curbing and controlling the appetite; that the article would satisfy hunger and remove excess water in all fatty deposits; that the "Regimen Plan" could do most everything medical science could do to help one attain one's goal; that excessive weight made cirrhosis of the liver much more possible than in slender folks; and that it had been shown that fat people were much more susceptible to cancer.

DISPOSITION: 2-4-64, 2-10-64, 3-24-64, 3-12-64, 3-12-64, 3-17-64, 2-19-64, 2-19-64, 3-4-64, 3-27-64, 3-12-64, 3-23-64, 2-27-64. Default—destruction.

7830. Regimen tablets (8 seizure actions). (F.D.C. Nos. 49737, 49744, 49779, 49783, 49785, 49883, 49894, 49903. S. Nos. 34-521/2 A; 301 A; 69-929 A; 39-991 A; 44-038 A; 18-339 A; 6-208 A; 13-492 A.)

QUANTITY: 19 156-tablet boxes and 59 78-tablet boxes, at Knoxville, Tenn.; 270 78-tablet boxes and 84 156-tablet boxes, at Jacksonville, Fla.; 420 78-tablet boxes and 6 156-tablet boxes, at St. Paul, Minn.; 106 78-tablet boxes and 26 156-tablet boxes, at Fort Worth, Tex.; 24 78-tablet boxes and 69 156-tablet boxes, at Albuquerque, N. Mex.; 540 78-tablet boxes and 180 156-tablet boxes, at Pittsburgh, Pa.; 199 78-tablet boxes, at Norfolk, Va.; 208 78-tablet boxes and 36 156-tablet boxes, at Manchester, N.H.

SHIPPED: Between 2-18-63 and 11-26-63, from New York, N.Y., by Drug Research Corp.

LABEL IN PART: (Box) "For Excess Weight Reduction by Appetite Control Regimen-Tablets * * * Distributor: Drug Research Corporation, New York, N.Y."

ACCOMPANYING LABELING: Circular entitled "Reduce with the Regimen Plan."

LIBELED: 1-24-64, E. Dist. Tenn.; 2-13-64, M. Dist. Fla.; 2-10-64, Dist. Minn.; on or about 2-10-64, N. Dist. Tex.; on or about 2-11-64, Dist. N. Mex.; 2-20-64, W. Dist. Pa.; on or about 2-25-64, E. Dist. Va.; 3-5-64, Dist. N.H.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for weight reduction and control by curbing and controlling the appetite; that the article would satisfy hunger and remove excess water in all fatty deposits; that the "Regimen Plan" could do most everything medical science could do to help one attain one's goal; that excessive weight made cirrhosis of the liver much more possible than in slender folks; and that it had been shown that fat people were more susceptible to cancer.

DISPOSITION: 5-4-64, 3-27-64, 4-1-64, 4-30-64, 3-23-64, 3-20-64, 4-2-64, 4-14-64. Default—destruction.

7831. Imperial Bee Cream With Royal Jelly and Age-Less Rinkle Reducing Cream. (F.D.C. No. 47152. S. Nos. 17-047/8 T.)

QUANTITY: 70 individually ctnd. 1¼-oz. jars of *Age-Less Rinkle Reducing Cream*, and 95 individually ctnd. 1¼-oz. jars of *Imperial Bee Cream With Royal Jelly*, at Knoxville, Tenn.

SHIPPED: Between 9-4-59 and 12-5-61, from New York, N.Y., by Grellva, Inc.

LABEL IN PART: (Jar and ctn.) "Age-Less Rinkle Reducing Cream by Krashé Helps to reduce wrinkles * * * note the amazing smoothness, exquisite beauty and more youthful look of your skin. * * * Grellva, Inc. New York 36, N.Y." and "Imperial Bee Cream With Royal Jelly by Krashé * * * by using this magical preparation wrinkles and lines seem to vanish. * * * Grellva, Inc., New York 36, N.Y."

ACCOMPANYING LABELING: Leaflet in *Age-Less Rinkle Reducing Cream* cartons reading in part "The World's New Wonder Product Rinkle Reducing Cream by Krashé * * * reduces wrinkles amazingly * * *"; placard reading in part "These wrinkles are getting on my nerves . . ."; salesman's catalog sheet reading in part "These wrinkles are getting on my nerves . . ."; salesman's catalog sheet entitled "Descriptions and Suggested Sales Presentations Avoid Wrinkles! Use The Fabulous Imperial Bee Cream With Royal Jelly by Krashé."

RESULTS OF INVESTIGATION: The placard and the salesman's catalog sheets had been supplied by the shipper for use in promoting sales of the article.

LIBELED: 2-23-62, E. Dist. Tenn.

CHARGE: *Age-Less Rinkle Reducing Cream*, 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for reducing skin wrinkles and preventing skin from undergoing the changes associated with the aging process; to perform miracles in reducing skin wrinkles and lines; stimulate the skin; and cause the skin to look more youthful; and that the article represented the latest and utmost achievement in the science of beauty and was the result of years of experimentation and research.

Imperial Bee Cream With Royal Jelly, 502(a)—when shipped, the name of the article, "*Imperial Bee Cream With Royal Jelly*" and statements in its labeling, contained false and misleading representations that the article, particularly because of its content of royal jelly, was effective in regeneration of the skin; enhancing the beauty of the skin; causing wrinkles and lines to vanish; and causing the skin to appear youthful.

Both articles, 502(e) (2)—when shipped, their labels failed to bear the common or usual name of each active ingredient.

DISPOSITION: 12-4-62. Default—destruction.

7832. Helauni's Ultra Wrinkle Night Cream and Wonder Lotion. (F.D.C. No. 49241. S. Nos. 30-782/3 X.)

QUANTITY: 720 2-oz. btl. of night cream and 1,440 4-oz. btl. of lotion, at Las Vegas, Nev., in possession of Helauni's Cosmetics.

SHIPPED: Between 7-1-62 and 12-27-62, from Los Angeles, Calif., by Bee Gee Laboratories.

LABEL IN PART: (Btl.) "Helauni's Ultra Wrinkle Night Cream * * * Las Vegas, Nevada" and "Helauni's Wonder Lotion * * * Las Vegas, Nevada."

ACCOMPANYING LABELING: Leaflets entitled "Helauni's Wrinkle Creme" and "Helauni's Wonder Lotion."

RESULTS OF INVESTIGATION: The leaflets were printed on the order of the dealer for the purpose of promoting sales of the articles.

LIBELED: 8-28-63, Dist. Nev.

CHARGE: 502(a)—when shipped and while held for sale, the names of the articles and statements in their labeling were false and misleading in that they represented and suggested that the articles were adequate and effective to remove tired lines and wrinkles (*Ultra Wrinkle Night Cream*) and remove tired lines and wrinkles around the eyes and forehead (*Wonder Lotion*); 502(b) (1)—the articles failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(e) (2)—the labels failed to bear the common or usual name of each active ingredient, including the quantity, kind, and proportion of alcohol; *Ultra Wrinkle Night Cream*: 502(a)—while held for sale, the labeling contained false and misleading representations that the article fed the underlying tissues; beautified and cleared adolescent skin (thereby implied a cure for acne conditions); helped renew Nature's own "Acid Mantle," or the blend of 7 "Guardian Acids" that form the protective mask or complexion mantle of the skin; renewed and recuperated the protective layers of the complexion mantle; and contained the proper chemical balance to replenish Nature's fundamental loveliness; and *Wonder Lotion*: 502(a)—while held for sale, the labeling contained false and misleading representations that the article gave the pores a chance to breathe as Nature intended and was compounded with many of Nature's minerals found in the western region of South America.

DISPOSITION: 10-21-63. Default—destruction.

7833. Sul-Ray mineral baths. (F.D.C. No. 48607. S. Nos. 12-645/7 V.)

QUANTITY: 6 ctns., each containing 5 5-oz. pkgs.; 8 cases, each containing 12 ctns. of 5 5-oz. pkgs.; and 172 cases, each containing 12 ctns. of 8 3-oz. pkgs., at Chicago, Ill., in possession of Walgreen Co.

SHIPPED: Between 9-20-62 and 10-10-62, from New York, N.Y., by Sulray, Inc.

LABEL IN PART: (Pkg.) "Sul-Ray Mineral Baths * * * Sole Distributors SULRAY, INC., New York, N.Y. [or "Tuckahoe, N.Y."] Active Ingredients Sodium sesquicarbonate, sodium sulfate, sodium bicarbonate, sodium chloride, starch and colloidal sulfur. Directions * * * See circular for complete directions."

ACCOMPANYING LABELING: Circular entitled "Sul-Ray Colloidal Sulfur Mineral Baths" and newspaper tearsheets entitled "Take the water cure."

RESULTS OF INVESTIGATION: The newspaper tearsheets had been clipped from a local newspaper and had been used by a dealer store in conjunction with a display of articles for the purpose of promoting sales of the article.

LIBELED: 1-11-63, N. Dist. Ill.

CHARGE: 502(a)—when shipped and while held for sale, the labeling contained false and misleading representations that the article was an adequate and effective treatment for tense nerves, nagging aches and pains, sore, aching muscles, overfatigue, insomnia, pains of arthritis and rheumatism, and insomnia caused by pain; that it helped improve muscular relaxation, helped circulation of blood and lymph, and helped increase depth of respiration; and (newspaper tearsheets only) that the article was adequate and effective as a treatment for nervous tension, fatigue, aches and pains, muscular miseries, sprains, stiff joints and insomnia.

DISPOSITION: 10-17-63. Consent—claimed by Sulray, Inc., New York, N.Y., and destroyed.

7834. Sunflo Air Purifier. (F.D.C. No. 43526. S. No. 12-457 P.)

QUANTITY: 24 devices at Chicago, Ill., in possession of S. S. Hollender, Inc.

SHIPPED: (12 devices) 5-7-59, from New York, N.Y., by Modern Aids, Inc., and (12 devices) 7-1-59, from New York, N.Y., by S. S. Hollender, Inc.

LABEL IN PART: "Sunflo Flowing Air Purifier."

ACCOMPANYING LABELING: Leaflets entitled "The Amazing New Sunflo Flowing Air Purifier" and two display cards reading in part "Asthma, Sinus, Hay-fever Relief * * * Sunflo."

RESULTS OF INVESTIGATION: The article appeared to be a portable cabinet enclosing a fan, a nylon filter, and two electronic ultraviolet ray tubes. The unit operates on 110-120 volts. In operation, the fan draws room air through the nylon filter and over the ultraviolet tubes and is then recirculated in the room.

The leaflets and one of the display cards were received from Modern Aids, Inc., and the other display card was prepared by the dealer.

LIBELED: 9-8-59, N. Dist. Ill.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for relieving allergies, asthma, simple coughs, sinus, colds, virus infection, hay fever, sinus congestion, and irritations of the respiratory tract; providing drugless relief from respiratory ills; helping to reduce spread of airborne disease germs; and that the device produced "ionized air" to relieve discomforts of respiratory conditions.

DISPOSITION: Modern Aids, Inc., claimant, filed an answer denying that the article was misbranded and a motion for removal of the case for trial in the Eastern District of New York. The Government opposed removal to that district but indicated that it had no objection to removal of the case to the District of New Jersey. On 11-2-59, an order was entered transferring the case to the District of New Jersey. Thereafter, the Government served upon the claimant a set of written interrogatories and a supplemental written interrogatory. The claimant filed objections to the interrogatories. The court subsequently sustained objections to some of the interrogatories and overruled the objections to the remaining interrogatories. The claimant then filed answers to interrogatories and, in addition, the Government filed answers to the interrogatories served upon it by the claimant. Thereafter, the case came on for trial before the court without a jury. At the conclusion of the trial the case was taken under advisement. On 2-20-62, the court handed down the following opinion (202 F. Supp. 147) :

WORTENDYKE, *District Judge*: "In this seizure action under Section 304 of the Food, Drug and Cosmetic Act, 21 U.S.C. § 334, the issue presented is whether the seized devices of claimant are misbranded, as defined in 21 U.S.C. § 352, by reason of false and misleading statements contained in their labeling respecting their efficacy for the treatment of human diseases or relief from their symptoms. Each of the devices was shipped in interstate commerce prior to seizure and was packaged in a carton containing leaflets entitled 'The Amazing New Sunflo Flowing Air Purifier.' Placards bearing the legend 'New Scientific Aid for Symptomatic Asthma, Sinus, Hay Fever Relief' were displayed in retail stores offering the device for sale after shipment. The libel of information charges that the printed matter accompanying each device represented that it is an adequate and effective treatment for relieving allergies, asthma, simple coughs, sinus colds, virus infection, hay fever, sinus congestion, and irritation of the respiratory tract; also that the device affords drugless relief from respiratory ills and helps to reduce the spread of air-borne disease

germs by producing 'ionized air' to relieve the discomforts of respiratory conditions.

"While claimant concedes that the leaflets and display cards describing and purporting to explain the functions of the device constitute labeling, *Kordel v. United States*, 1948, 335 U.S. 345; *United States v. Lee*, 7 Cir. 1942, 131 F. 2d 464, claimant emphatically denies that such labeling contains the representations charged in the libel, and insists that the statements which are contained in the labeling are not false. Claimant asserts that the device affords palliative relief from the breathing stress and breathing discomforts associated with such conditions or diseases as are therein enumerated; i.e., that the user of the device 'may enjoy new comfort and palliative relief from breathing discomforts which are due to allergies, asthma, simple coughs, colds and virus infection, hay fever, sinus congestion, and simple irritation of the mucous membrane lining the respiratory tract.' Mitigation of the symptoms is not the equivalent of cure or arrest of a disease; but relief from breathing discomforts associated with the specific respiratory diseases enumerated in the labeling may create the impression in the lay mind that the device is represented to be a remedy or cure for a particular disease. See *D.D.D. Corporation v. Federal Trade Commission*, 7 Cir. 1942, 125 F. 2d 679; *Aronberg v. Federal Trade Commission*, 7 Cir. 1942, 132 F. 2d 165; *Rhodes Pharmacal Co. v. Federal Trade Commission*, 7 Cir. 1953, 208 F. 2d 382, rev'd 1955, 348 U.S. 940.

"The device in question consists of a cabinet or box, approximately the size and shape of a table radio, which contains a small electric motor-driven fan by means of which air is drawn through a filter forming the rear wall of the box and is exhausted through the front grilled face of the cabinet into the ambient air. In its passage through the box, some of the air is exposed to ultra-violet rays emitted by two electric bulbs contained in the device. The components of the device are alleged to perform, in combination, the following functions: The filter forming the rear wall of the box removes pollen, other air-borne allergens, and dust from the air. The ultra-violet light within the box kills bacteria and viruses in the air which passes by and around the bulbs, by creating ozone in that air. The alleged negative ionization of the air, in combination with the ozone produced by the ultra-violet lamps, is claimed to have a bactericidal effect upon air-borne germs.

"There was evidence that air flows through the device at the rate of 41.5 cubic feet per minute, according to measurements made by a pilot tube in conjunction with a pressure-measuring device and a thermocouple anemometer. The average arrestance of dust achieved by the filter was 14.6%. Ragweed pollen penetrated the device to the extent of manifesting its presence microscopically on the downstream surface of the front grille. Tobacco smoke passed freely through the device, and the reduction of particulate matter in a room with a volume of 1800 cubic feet was obtained only to the degree of 17% of the concentration to be found in a room of similar volume in which no such device was operated. For the purpose of determining the efficacy of the device for the removal of dirt from the air, two experiments were performed; one for a period of 41 hours, and the other for a period of 16 hours. Three similar, in-line office rooms were selected, and two air samplers were placed in the center room, with glass tubes connecting the samplers with the end rooms, and extending through the dividing walls separating the room in which the samplers were located from the end rooms. One of the end rooms contained an operating Sunflo device; the other, none. All of the rooms were unoccupied for practically the entire period of the test. The doors and windows were closed and locked, and no air conditioner was functioning therein. The air was drawn from the control room and from the test room through the air samplers, and the particulate matter in the air was deposited on paper tape in each sampler, causing spots of discoloration thereon. The density of each spot reflected the quantity of dirt collected in one hour of time. The spots on these tapes were evaluated by determining the quantity of light transmitted through them, as indicating the amount of the particulate matter suspended in the air of the test room and of the control room. The value of each spot was graphed and graphs for the test and control rooms were prepared. It was found that there was no significant difference in the amount of dust suspended in each of the rooms compared.

"The ultra-violet emission rate of the Sunflo lamps was found to be 43 and 11 microwatts per square centimeter, at distances of six inches and one foot respectively. The device was found to deliver approximately 250,000,000 negative ions per second, or 13,000 negative charges per cubic centimeter at the front grille, and 400 to 500 negative charges per cubic centimeter at a distance of six feet in front of the grille.

"A medical specialist in allergies expressed the opinion that an air filter, if interposed between a source of air-borne allergens and an asthma sufferer, might reduce his exposure to the allergens in proportion to the efficiency of the filter, provided that the patient were otherwise insulated from the source of the allergens. Such insulation is impossible in the case of ambient room dust. A reduction of particulate matter in a room to the extent of only 17% would not, in the opinion of the Government's medical expert, accomplish a noticeable diminution of symptoms resulting from the presence of air-borne allergens. Therefore, the device would be of little value in the treatment of a sufferer from ragweed allergy. Cardiac asthma would obviously not respond to treatment by the use of the device, and such a disease might become progressively worse if the device were solely relied upon for its treatment. Breathing discomforts due to colds or virus infections would also fail to respond to the use of the device; although coughs and sinus congestion, due to filterable particulate matter in the air, might be relieved in some degree. The ultra-violet radiation and its ozone product has little, if any destructive effect on air-borne micro-organisms. Allergies due to infection, or resulting from ingestion of food, would not respond to the use of an air filter. Because of its limited capacity to arrest ragweed pollen, and its retention of only 14% of particulate matter from air passing through its filter, the device is ineffective for the treatment of allergies due to inhalation of air-borne allergens. Only three out of every ten cases of asthma are of allergic origin. The filtration feature of the device, therefore, is of little utility for treatment in the majority of asthma cases. Excepting cases of sinus congestion caused by air-borne allergens, the device is not effective in the treatment of coughs, colds, virus infections, or sinus difficulties. The negative ions which are said to be produced by the device, are ineffective in the treatment of respiratory diseases.

"In efforts to refute the authoritative opinions of the six amply qualified expert medical and scientific witnesses for the Government, claimant called two witnesses. One of the latter was the designer of the device in question; the other a general medical practitioner, whose testimony was based upon unscientific procedures and hearsay information.

"A large part of the testimony given by the designer of the device was critical of the testing techniques used and contradictory of the opinions expressed by the Government witnesses. Affirmatively, he testified that the device consisted of a filter, comprised of flocked nylon fibers, through which the air is drawn into the device. The openings in the grille, which forms the front of the device, are so designed and arranged as to aid in the diffusion of the discharging air to enhance the over-all efficiency of the unit. The two ultra-violet lamps within the shell of the device are said to emit ultra-violet rays of 1849 and 2537 wave lengths, and are partially surrounded by a special metallic shield upon which the emitted rays impinge. The designer also claimed that a static electric charge, positive in nature, equivalent to 60 volts, is induced on the nylon filter by the passage of the air through the same at a velocity of approximately 200 feet per minute, in atmospheres of from forty to eighty-five percent relative humidity. He further testified that the device is constructed so that it can only give off negative charges of electricity. This is accomplished by means of the special metallic plates partially surrounding the ultra-violet lamps. The bulbs of these lamps are designed and manufactured by Westinghouse Electric Manufacturing Company, and are known by its catalogue number 794H. The thickness of the glass envelopes of these lamps, in combination with the chemical composition of the bulbs, is said to create a high angstrom measure of radiation. It is the contention of the claimant that the ultra-violet lamps in the device perform three major functions: (1) they produce a small amount of ozone, the effect of which is to deodorize, and to kill bacteria and virus in the air; (2) the effect of the ultra-violet emission is bactericidal or germicidal, by reason of its wave lengths; and (3) the ultra-violet emission is the principal productive source

of the negative ions in the air as it flows through the unit. In addition to these features, claimant says that the so-called ion grilles are coated with graphite to counteract the fatigue effect from photoelectric ion production; i.e., to offset its diminishing ion-producing capacity. A grid leak is attached to the plate which grounds out its positive charge and renders constant the flow of electrons into the plate without impairment of the intensity of their emission. Another feature upon which the claimant predicates its claims of the efficacy of the device is its structural provision for recirculation of the air. It is asserted in this connection that the negative ionization of the air-borne particles and other contaminants enhances the capacity of the positively charged filter to pick them out of the air-stream as it passes through the device. In cases of smoke-laden air, which is said to be positively charged, an attraction is created between the positively charged particles thereof and the negative ions produced by the device, which changes the charge of the smoke particles either to a neutral or to a negative phase. It is contended, therefore, that the recirculation of the smoke particles through the machine, after having been neutrally or negatively charged, enhances the capacity of the positively charged fibers of the filter to attract and hold them. A further theory urged by the claimant is that the emission of negative ions, created within the device, into the outer surrounding air neutralizes positively charged particles in that air, and thereby prevents their mutual repulsion and causes them to agglomerate into larger masses, more readily susceptible of arrest by the filter.

"Claimant contends that the efficacy of the device to refresh and deodorize stale air has not been questioned or refuted by any competent evidence adduced in the case. With this contention we agree. However, we recognize that refreshment and deodorization of stale air to the extent resulting from single or even from many passages of the air through the device is neither probative nor conclusive of the efficacy of the device for the therapeutic purposes set forth in the labeling. Assuming the arrestance capacity of the filter, the static charge given to the fibers thereof through the friction of the passage of the air therethrough, the addition of the ozone resulting from the ultra-violet light emissions, and the ionization of the air in its transit through the device, these factors do not, either singly or in combination, serve to render the device efficacious as 'an adequate and effective treatment for relieving allergies, asthma, simple coughs, sinus colds, virus infection, hay fever, sinus congestions and irritation of the respiratory tract' or to relieve respiratory ills or inhibit the spread of air-borne disease germs. To relieve is to free wholly or partly from something painful or disagreeable, or from its effects.

"The Court takes judicial notice of the fact that atmospheric air contains particulate matter and serves as a carrier of bacteria. To the extent that a given volume of such air is drawn through a nylon filter, some, at least, of the particulate matter is screened from that air. As this screened air is then passed through ultra-violet rays, it is sterilized to a degree and its bacteria count is reduced. Doubtless the air screen with which we are immediately concerned becomes negatively ionized. When the stream of air emerges from the device, after passage through it and into the circumambient air, there is no means by which the molecules of the volume of air which has passed through the device can be channeled or confined so as to be protected from contamination by contact with the surrounding atmosphere. The emission of a volume of air from the front of the device permits immediate diffusion of the molecules of that volume throughout the entire air space within the area in which the device is operating and no means are provided for recirculating, on a second trip through the device, the same air which had previously passed through it. Therefore, the theory of agglomeration of particulate matter and bacteria as a result of the electrical charges conferred or transferred by the passage of a given volume of air through the device, and the consequent improvement of the arrestance afforded by the filter upon the next round of the travel of these agglomerated contaminants, is illusory. The patient sufferer from one or more of the diseases mentioned in the labeling is thus unjustifiably induced, by the representations therein, to hope that, if the device operates long enough, and adverse and intruding atmospheric currents permit, the air volume in the room will ultimately become purer and safer for him to inhale. There was no relia-

ble evidence in the case from which a reasonable inference could be drawn that the operation of claimant's device at a particular location, within a given volume of air space, for any specific period of time, would have any alleviative or therapeutic effect upon an individual occupying that air space, who might be suffering from one or more of the ills named in the labeling here considered.

"Assuming that the seized device is therapeutically inefficacious, does the evidence support the libellant's contention that the labeling is false or misleading in its representation that sufferers from the ailments named would be induced to buy and use the device in efforts to secure relief from the effects of those diseases? Claimant would answer this question in the negative, upon the authority of *D.D.D. Corp. v. Federal Trade Commission*, *supra*; *Jarvis v. Shackelton Inhaler Co.*, 6 Cir. 1943, 136 F. 2d 116; and *Rhodes Pharmacal Co. v. Federal Trade Commission*, *supra*. In *D.D.D. Corp.*, the Federal Trade Commission's order found false and misleading the advertising of the proprietor's external liquid applications as effective relief for itching. The Court of Appeals (per Major, C.J.) stated (p. 682): 'We see no reason why petitioner should not be permitted to represent its product as a relief for itching. It does not cure either the itch or its cause, but it does afford relief. * * * The words "relief from itching" could, in our minds, carry no implication to the public that the product was a permanent cure either for the symptom or the disease.'

"In *Jarvis* the Court of Appeals affirmed the District Court in enjoining a local postmaster from obeying a fraud order of the Acting Postmaster General. The advertising material there involved represented that the proprietor's medicinal compound and apparatus had proven helpful as a palliative, relief and assistance in cases of colds, sinus irritations, and hay fever, and contained a 'money-back' guarantee. It was not represented as a cure-all panacea. It was conceded that it was not invariably efficacious.

"The *Rhodes Pharmacal* case affirmed the Federal Trade Commission's cease-and-desist order by a finding that although the proprietor's product afforded (p. 388): 'relief for the pain and discomfort incident to many rheumatic and arthritic conditions' and '[t]he duration of time that such relief was afforded differed with the individuals who used' it, the product would not furnish permanent relief or effect a cure of rheumatic or arthritic conditions. The Court modified the Commission's order to enjoin representations that the product would afford permanent rather than any relief from the discomforts of the named ills.

"Proprietor's contention that his product was advertised not as a remedy but as providing relief from delayed menstruation did not enable him to withstand the Commission's order in *Aronberg v. Federal Trade Commission*, *supra*, because, as the Court said (p. 168): 'The term "relief" is not of definite connotation or entirely free from ambiguity; in a common sense, it connotes permanent removal of organic or functional disturbance, as distinguished from alleviation of discomfort.' The Court found (p. 169), that '[t]he consensus of the expert testimony was that petitioner's preparations are not competent, safe, or reliable as a relief for delayed menstruation because of the heavy dosage of drugs contained in each capsule.'

"The representations in the present case which the Government criticizes as false and misleading are to be found in the leaflet entitled 'The Amazing New Sunflo Flowing Air Purifier' and in the display card entitled 'New Scientific Aid for Symptomatic Asthma, Sinus, Hay Fever Relief' previously herein referred to. The leaflet purports to explain how the user may enjoy new comfort and palliative relief from breathing discomforts due to allergies, asthma, simple coughs, colds and sinus infection, hay fever, sinus congestion and simple irritation of the mucous membrane lining the respiratory tract (including nose, throat and bronchi). The leaflet claims four potentials for the device: (1) promotion of helpful palliative relief of certain asthma and hay fever symptoms, such as sneezing and associated breathing difficulty, achieved by the filtering out of allergens, pollens, soot, dust, dirt and other contaminants whereby the sufferer is caused to 'feel better fast' and enabled to breathe more easily in consequence of the removal of irritants that constantly aggravate swollen membranes; (2) production of 'ionized' air which, when inhaled, may be influential in shrinking swollen membranes of respiratory passages, and may aid in speeding recovery from cold or virus symptoms and in protecting from infection by air-borne disease germs; (3) compensation for electron deficiency in ambient air through its enrichment by the

ionization of the air flowing from the device; and (4) deodorization of the ambient air and destruction of viruses and other air-borne germs therein by means of ozone produced by the two ultra-violet bulbs within the device. In sum, it is claimed that the device affords palliative relief from symptoms of various diseases, aids in shrinking swollen membranes of respiratory passages, compensates for electron deficiencies in the air, and serves to deodorize the air and destroy virus and other air-borne germs therein. The display card represents that the device affords effective relief from breathing distress due to allergies, asthma, simple coughs and colds, sinus, hay fever or air-borne irritants. It is stated that the device produces, for inhalation by the sufferer, healthful ionized air almost completely free of air-borne allergens, dust carried bacteria, pollen, and impurities. The resulting electron-enriched air is said to promote quick, palliative, drugless relief from the respiratory ailments above mentioned, by aiding the lungs and throat in clearing themselves from congestion and foreign matter and releasing bronchial asthma spasms. 'Ionized air' as used in the advertisement is therein defined as air which is electronically treated by ultra-violet sun-tubes in the device, so that the air becomes revitalized and energized. In the proprietor's language, 'In go dust, germs, pollen, odors, allergens, and other irritants . . . OUT comes the pure, safe, fresh and beneficial kind of air you should breathe—plus an increased supply of "activated oxygen" that promotes immediate, pleasant relief with every breath you take. * * * It purifies as it filters as it deodorizes as it recirculates a whole roomful of enriched, healthier-to-breathe air every few minutes.'

"The Court finds that the seized device is harmless, *per se*; and that it filters some particulate matter from and reduces, to a degree, the bacteriological and virus content of such air as is drawn into and discharged from the device. No person who had used the device while suffering from any of the diseases mentioned in the labeling testified respecting the effect of the operation of the device upon the discomforts of the sufferer. The presence of ozone in the air discharged from the device is easily perceptible to the olfactory sense when inhaled as it leaves the front grille. No evidence was presented of the effect of the discharged air upon pervasive odors in the surrounding air. Air-borne smoke passed readily through the device. If, as the claimant contends, air which is discharged from the device is ionized, the evidence preponderates that it is inefficacious to eliminate the symptoms of any of the diseases or conditions mentioned in the labeling. The device does not purify as it filters the air; nor does it deodorize or recirculate a whole roomful of enriched air every few minutes.

"The device is misbranded, because its labeling is in some respects false, and in other respects misleading. The device and its labeling are condemned, and an appropriate decree will be entered. However, after entry of such decree, and upon payment of the costs of these proceedings, and execution of bond as provided in 21 U.S.C. § 334(d), the seized devices may be delivered to the owner thereof, to be brought into compliance with the provisions of Chapter 9 of Title 21, pursuant to the requirements of said Section.

"Submit decree and order accordingly."

Pursuant to the above opinion, the district court entered a decree, on 6-4-62, providing for condemnation of the article and its release under bond to be brought into compliance with the law. The case was appealed by the claimant to the United States Court of Appeals for the Third Circuit and, on 6-18-63, such court handed down a *per curiam* opinion in which it stated that on review of the record it found no error and affirmed the decision of the district court.

7835. Negative ion generator. (F.D.C. No. 48412. S. No. 36-317 V.)

QUANTITY: 25 devices at New Orleans, La.

SHIPPED: Between 9-27-62 and 10-2-62, from Chicago, Ill., by Radex Corp.

LABELS IN PART: "Lectric-Aire Negative Ionizer," "Radex Corp. Chicago 14, Ill.," and "Distributed by Justice Enterprises, Inc."

ACCOMPANYING LABELING: Leaflets entitled "Lectric-Aire Negative Ion Generator," "Special Features * * * Form 5627S," and "References"; reprints entitled "Can Negative Ions Added to the Air you Breathe Improve your Well-Being?" (House Beautiful, February 1961), "A Reader's Digest Reprint Ions Can Do Strange Things To You," "April, 1962 Prevention The Magazine For Better Health," and "Des Moines Sunday Register Doctor's Notebook Ozone Has Fresh Air Smell, But It's Poison"; pamphlets entitled "Bibliography of General Literature on Air Ionization," "Bibliography of Scientific and Medical Papers on Air Ionization and Its Effects," and "Ion Therapy and Health"; testimonial letters to Radex Corp. signed "Frances Adams," "Harry J. Stegman," and "J. F. Tardba"; folder entitled "Allergy"; and form letters on Electric-Aire Purifier Division letterhead, beginning "Thank you for requesting literature and information . . ."

RESULTS OF INVESTIGATION: Investigation indicated the article to be a mahogany-colored, bakelite cabinet, $15\frac{1}{4} \times 8\frac{1}{2} \times 8\frac{3}{4}$ inches, containing an aluminum mesh filter, a charcoal filter, power pac, tritium ion source, air blower, and intake and exhaust grills.

LIBELED: 12-11-62, E. Dist. La.

CHARGE: 502(a)—when shipped and while held for sale, the accompanying labeling contained false and misleading representations that the article would stimulate the nasal cilia to remove airborne pollutants; help prevent infant strangulation from mucus buildup; make burns dry out faster, heal fast, with less scarring; reduce the need for skin grafting; promote better sleep; relieve asthma and hay fever; rebuild energy; reduce high blood pressure caused by hypertension; and eliminate, relieve, or reduce pain.

DISPOSITION: 9-17-63. Consent—claimed by Justice Enterprises, Inc., of New Orleans, La., for relabeling to be performed by the shipper in Chicago, Ill.

7836. Swedex massage machine. (F.D.C. No. 47971. S. No. 11-352 T.)

QUANTITY: 10 devices at Pittsburgh, Pa., in possession of Mrs. Marie C. Mayhew.

SHIPPED: 4-26-62, from St. Paul, Minn.

LABEL IN PART: "Swedex Massage Machine."

ACCOMPANYING LABELING: Leaflets entitled "Svensk Massage" and "Here Is Your Swedish Massage Machine * * * Manufactured by Haldeman Homme, Swedex Division, * * * St. Paul 14, Minnesota"; sales manuals entitled "How To Fight Poor Health Flabbiness Vague Aches and Pains."

RESULTS OF INVESTIGATION: Descriptive literature and photographs indicated that the article was a vibrating massage cushion. The device contained 2 5- to 6-inch discs which revolved or oscillated under a loose, vinyl plastic cover to provide the massage motion. The controls and motor housing were mounted on top of one end of the cushion.

LIBELED: 8-14-62, W. Dist. Pa.

CHARGE: 502(a)—while held for sale, the accompanying labeling contained false and misleading representations that the article was adequate and effective to step up the heartbeat; increase blood circulation; increase oxygen intake; strengthen abdominal muscles; improve contour and body lines; provide gentle intestinal massage; help balance body weight; soothe nerves; improve the elimination of waste; aid circulation; relieve stiff and aching muscles; and that the article was an important aid in counteracting indigestion, constipation, insomnia, nervous tension, and migraine headaches.

DISPOSITION: 9-25-63. Consent—claimed by Mrs. Mayhew, and released under bond for relabeling.

7837. Safe-T-Sun Health-Tan Sun Lamp. (F.D.C. No. 49491. S. Nos. 3-843/4 X.)

QUANTITY: 119 devices at Baltimore, Md.

SHIPPED: 4-8-63, from New York, N.Y., by Celebrity Merchandisers, Inc.

LABEL IN PART: (Lamp bulb) "Jayne Mansfield Sunlamp [or "Health Tan Sun Lamp" or "Safe-T-Sun Health-Tan Sun Lamp"] * * * Richmond, Va."

ACCOMPANYING LABELING: Leaflets entitled "Operating Instructions for the Jayne Mansfield Health-Tan Sunlamp" and brochures entitled "Jayne Mansfield Patented Health-Tan Sunlamp with exclusive 'Can't Burn' Feature!"

RESULTS OF INVESTIGATION: Investigation indicated that the device was an electrical lamp fixture containing a 275-watt ultraviolet lamp and holder for the Mylar and/or acetate filters. The lamp was supported on a tripod for floor or table use, or by a clamp unit.

LIBELED: 10-29-63, Dist. Md.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for relieving tired back, stiff neck, arthritic-like pains, skin problems, aching muscles, and toning the skin; that the filter would permit unlimited use of the lamp to provide a tanning effect without painful burning; and that the article could be used as a "sun lamp that can't burn."

DISPOSITION: 12-30-63. Consent—claimed by John W. Dornbusch, t/a Celebrity Merchandisers of Baltimore, Baltimore, Md., and ordered released for relabeling.

7838. Lady Ample device. (F.D.C. No. 48938. S. No. 38-566 V.)

QUANTITY: 205 unlabeled devices in boxes at Metairie, La., in possession of Lady Ample, Inc.

SHIPPED: Between 1-8-63 and 3-12-63, from Texas City, Tex., by Lloyd Lambert.

LABEL IN PART: (Inside box cover) "Instructions for Assembly and Operation."

ACCOMPANYING LABELING: Brochures entitled "The Success of Lady Ample."

RESULTS OF INVESTIGATION: The article in each box contained 3 pink, plastic funnel-shaped cups of varying sizes, rubber or plastic tubing, and 1 aspirator designed to produce a vacuum when fastened to a faucet.

The brochures were printed by the dealer using as a guide a similar brochure furnished by the supplier. They were used to promote sales of the article.

LIBELED: 5-3-63, E. Dist. La.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that use of the article would increase the size of the breasts and that every normal, healthy woman, regardless of her age, could become a "Lady Ample"; that science and medical research had shown that female breasts develop naturally only when the tissues were adequately fed with the nourishment carried by the circulatory system, and that such feeding built the breast to nature's intended firmness and fullness; that since the breasts were appendages to the body without movement of their own, vigorous exercise was necessary to maintain the re-

quired circulation; that today many women do not get enough healthful exercise to maintain proper circulation to the breasts; that lack of exercise allowed the breasts to become flabby and sagging, receding to less than normal size or, in the case of many young women, never to fully develop; that doctors have stressed the fact that the only way a breast could be properly exercised was by some gentle medium that promoted circulation and toned up the underlying tissue; that the "*Lady Ample*," an instrument, had been developed that safely and gently exercised the breasts right in the privacy of the home; that the "*Lady Ample*" was actuated by gentle pulsating vacuum, and was developed exclusively to promote tissue-feeding circulation in the breast by safe, passive exercise; that when the device was used as directed, the alternate expanding and releasing of the breasts caused an increase in the flow of life-giving blood to its tissues; that in this way, the breast was given food so it could grow to its natural attractive shape; that the "*Lady Ample*" instrument was absolutely safe to use; that the average user of the "*Lady Ample*" often saw measurable results within three weeks after regular use of the instrument had begun; that full development could be achieved by users susceptible to this type of treatment in from 2 to 5 months; and that once the fully desired size of the breast had been developed, use of the "*Lady Ample*" once every several weeks would retain the natural fullness.

DISPOSITION: 10-17-63. Default—30 devices delivered to the Food and Drug Administration and remainder destroyed.

DRUG FOR VETERINARY USE*

7839. Millers hog and poultry wormer liquid. (F.D.C. No. 46522. S. No. 26-662 T.)

QUANTITY: 23 1-qt. btls. and 15 1-gal. btls., at Francesville, Ind.

SHIPPED: 8-11-61, from Toledo, Ohio, by Miller Chemical Co.

LABEL IN PART: (Btl.) "MILLERS PIPERAZINE LIQUID HOG & POULTRY WORMER ACTIVE INGREDIENT EACH 100 CC CONTAINS 17.08 GRAMS OF PIPERAZINE BASE HEX-A-HYDRATE MANUFACTURED BY MILLER CHEMICAL COMPANY * * * TOLEDO OHIO—DIRECTIONS."

LIBELED: 11-6-61, N. Dist. Ind.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for removing or controlling nodular and roundworms from swine and roundworms (*Ascaridia galli*) from poultry.

DISPOSITION: 12-15-61. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF IMITATION OF AND SALE UNDER NAME OF ANOTHER DRUG**

7840. Imitation Miltown tablets and Diuril tablets. (F.D.C. No. 45231. S. Nos. 4-661/2 R.)

INFORMATION FILED: 6-19-61, Dist. Columbia, against Discount Drug Wisconsin, Inc., Washington, D.C.

*See also Nos. 7782, 7802, 7821.

**See also No. 7813.

ALLEGED VIOLATION: On 8-15-60, the defendant caused to be introduced into interstate commerce, by sale and delivery in the District of Columbia, one vial of *imitation Miltown tablets* and one vial of *imitation Diuril tablets*.

CHARGE: 502(i) (2)—when introduced into interstate commerce, as described above, the articles were imitations of other drugs, namely, Miltown and Diuril; and 502(i) (3)—the articles were offered for sale under the names of other drugs, namely, Miltown and Diuril.

PLEA: Nolo contendere.

DISPOSITION: 3-19-62. \$200 fine, with payment suspended.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 7781 TO 7840

PRODUCTS

	N.J. No.		N.J. No.
A-D Vitamins	7826	Depolaray	³ 7803
A-E Plus capsules.....	7826	Chair	³ 7803
Age-Less Rinkle Reducing Cream	7831	Junior	³ 7803
Air Purifier, Sunflo.....	¹ 7834	New	³ 7803
Amitone tablets.....	² 7823	Depolatron and Depolatron Chair	³ 7803
Amphetamine sulfate tablets....	7797	Devices	³ 7803-7810,
dextro-, sulfate capsules.....	7797		7818-7820, ¹ 7834-7838
sulfate tablets.....	7796, 7797	Dexabarb #1 capsules.....	7796
Androgenic substance	7781	Dextra Sugar.....	7824
Animal tissues.....	7784	Dextro-amphetamine sulfate cap-	
Asthma, remedy for (device)....	¹ 7834	sules	7797
Belladonna ointment	³ 7789	tablets	7796, 7797
Bio-Atric elixir.....	7781	Dextro-amphetamine sulfate	
tablets	7781	with amobarbital capsules..	7796
Blood Specimen Carriers.....	³ 7803	Diuril tablets, imitation....	7813, 7840
Bonsul tablets.....	7786	Electropad	³ 7803
Bust developer (device).....	7838	Elixir Bromide and Chloral....	³ 7789
C-112 Wetting Solution.....	7817	Tungylate	³ 7789
Calamine lotion, phenolated....	³ 7789	Estrogenic substance.....	7781
Cal-Re-Low dietary supplement..	7825	Feed, medicated.....	³ 7782, 7788, 7821
Carotene and vitamin E capsules	7826	Fenadin capsules	³ 7789
Coal-tar colors.....	7812	Formula 9 vitamin capsules....	7828
Codeine sulfate tablets.....	³ 7789	Gastric and duodenal ulcers,	
Color additive violation.....	7812	remedies for.....	³ 7794, 7795
Comfrey leaf, dried.....	7802	Geri Bio Vites Vitamin Formula	
tablets	7802	tablets	7801
Compound cathartic pills.....	7799	Gest-O-Zyme tablets.....	7801
Corticotropin gel injection.....	7822	Hair and scalp conditions, rem-	
Cosmetics (subject to the drug		edy for.....	7828
provisions of the Act)....	7831, 7832	Halibut liver oil capsules.....	7826
Cy-B-7 Multivitamin capsules..	7828	Hay fever, remedy for (device) -	¹ 7834

¹ (7834) Seizure contested. Contains opinion of the court.

² (7823) Seizure contested.

³ (7782, 7783, 7793, 7794, 7803) Injunction issued.

	N.J. No.		N.J. No.
Helauni's Ultra Wrinkle Night Cream and Wonder Lotion	7832	Pep-O-Vite tablets	7801
Hog and poultry wormer liquid, Millers	7839	Phenobarbital tablets	7797
Imperial Bee Cream With Royal Jelly	7831	Phenothiazine powder	7811
Jettup B Complex with B ₁₂ tablets	7815	Val-A	7811
KC 555 and KC 555 Preparation	³ 7783	Potassium arsenite, solution	³ 7789
LSD (D-lysergic acid diethylamide)	7785	Prenatal tablets	7792
Lady Ample device	7838	Prescription drugs	7787, 7790
Laxative without required warning statement	7799	Prophylactics, rubber	7818-7820
Lecithin-safflower oil capsules	7826	Radioscope	³ 7803
Massage machine, Swedex	7836	Rauwolfia serpentina tablets	7796
Mathison Electropsychometer	7808	Reducing preparations	7829, 7830
Mattress, Vibra-Matic	7809	Regimen tablets	7829, 7830
Methyltestosterone tablets	7796	Research Model devices	7807
Micro-Dynameter devices	7804-7806	Reserpine alkaloid tablets	7796
Micro-Tabulometer device	7804	powder and tablets	7814
Milk of Bismuth	³ 7789	Respiratory conditions, remedy for (device)	¹ 7834
Millers hog and poultry wormer liquid	7839	Safe-T-Sun Health-Tan Sun Lamp	7837
Miltown tablets, imitation	7840	Safinol capsules	7826
Mineral baths, Sul-Ray	7833	Salol (phenyl salicylate) tablets	³ 7789
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Neurolinometer device	7804	Secobarbital sodium capsules	7797
Nitroglycerine, digitalis, and Strophanthus compound tablets	³ 7789	Sinusitis, remedy for (device)	¹ 7834
Nitroglycerine triturates	³ 7789	Skin rejuvenator	7831, 7832
tablets	³ 7789	Sleep-machine device and accessories	7810
Nutri-Bio food supplement	7816	Soybean lecithin capsules	7826
Obesity, remedies for. <i>See</i> Reducing preparations.		Speed-A-Vite capsules	7826
Opium, tincture of	³ 7789	Stilbestrol tablets	7796
Oscilloclast and Regular Push-button Shortwave Oscilloclast	³ 7803	Stomach disorders, remedy for	² 7823
Oscillotron	³ 7803	Strychnine sulfate tablets	³ 7789
Galvanic Five-In-One Short-wave	³ 7803	Sulfadiazine tablets	³ 7789
Sinusoidal Four-In-One Short-wave	³ 7803	Sul-Ray mineral baths	7833
Sweep	³ 7803	Sunflo Air Purifier	¹ 7834
Penicillin G potassium tablets	7797	Supab-Na-Sal tablets	7800
Pentobarbital sodium capsules	7797	Supainex capsules	7800
		Super-Acto-C tablets	7801
		Super Egg Atoms feed, Medicated	7821
		Insta Protein Wafers	7801
		Optimum capsules	7801
		Swedex massage machine	7836
		Thorson's Soap Lake Salts, Effervescent Soap Lake Salts, Concentrated Soap Lake Water, and Soap Lake Ointment	³ 7793

¹ (7834) Seizure contested. Contains opinion of the court.² (7823) Seizure contested.³ (7782, 7783, 7789, 7793, 7794, 7803) Injunction issued.

	N.J. No.		N.J. No.
Throat lozenges-----	7798	Veterinary preparations-----	³ 7782,
Ulcers, gastric and duodenal,			7786, 7788, 7811, 7821, 7839
remedies for-----	³ 7794, 7795	Vibra-Matic mattress-----	7809
Urginin tablets-----	7791	Vitamin preparations-----	7822, 7826-7828
Val-A phenothiazine-----	7811	Water, distilled-----	7784
Vanul aqueous suspension--	³ 7794, 7795		

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

	N.J. No.		N.J. No.
Agricultural Div., American Cyanamid Co.:		Celebrity Merchandisers, Inc.:	
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Allied Latex Sales Co.:		Certified Sleep Co.:	
rubber prophylactics-----	7819	Vibra-Matic mattress-----	7809
Amco Drug Products Co., Inc.:		Cobian Enterprises:	
Bonsul tablets-----	7786	throat lozenges-----	7798
American Cyanamid Co.:		Cole, M. H., D.C.:	
medicated feed-----	7788	Research Model devices-----	7807
<i>See also</i> Agricultural Div.		Comfrey Supplies (N.Z.), Ltd.:	
Arcon Manufacturing Co. (Mathi- son Manufacturing Co.):		dried comfrey leaf and comfrey tablets-----	7802
Mathison Electropsychometer--	7808	Copley, Bernard:	
Barnetts, Inc.:		LSD (D-lysergic acid diethyla- mide)-----	7785
rubber prophylactics-----	7819	Cumberland Manufacturing Co.:	
Barth Levitt Products:		compound cathartic pills-----	7799
various vitamin, mineral, leci- thin, and oil products-----	7826	Discount Drug Wisconsin, Inc.:	
Basic Remedies, Inc.:		imitation Miltown tablets and Diuril tablets-----	7840
vitamin capsules-----	7828	Dixie Drugs. <i>See</i> Michelson, Herman.	
Beacon Div. of Textron, Inc.:		Drug Research Corp.:	
Medicated Super Egg Atoms feed-----	7821	Regimen tablets-----	7829, 7830
<i>See also</i> Professional Feeds.		Elder, Paul B., Co.:	
Bee Gee Laboratories:		Sargon Pills and Urginin tablets-----	7791
Helauni's Ultra Wrinkle Night Cream and Wonder Lotion--	7832	Ellis Research Laboratories, Inc.:	
Bio-Factor Laboratories:		Micro-Dynameter devices--	7805, 7806
Bio-Atric tablets and Bio-Atric elixir-----	7781	Elmore Milling Co., Inc.:	
Blackman, Stanley, Laboratories, Inc.:		medicated feeds-----	³ 7782
reserpine powder and tablets--	7814	Foundation for the Advancement of Chiropractic Research, Inc.:	
Brooks, K. E.:		Research Model devices-----	7807
Vanul aqueous suspension-----	³ 7794	Fritzsche Bros., Inc.:	
Burrough Bros. Manufacturing Co.:		coal-tar colors-----	7812
various pharmaceutical prod- ucts-----	³ 7789	Gaboff, Benjamin:	
		various pharmaceutical prod- ucts-----	³ 7789

³ (7782, 7783, 7789, 7793, 7794, 7803) Injunction issued.

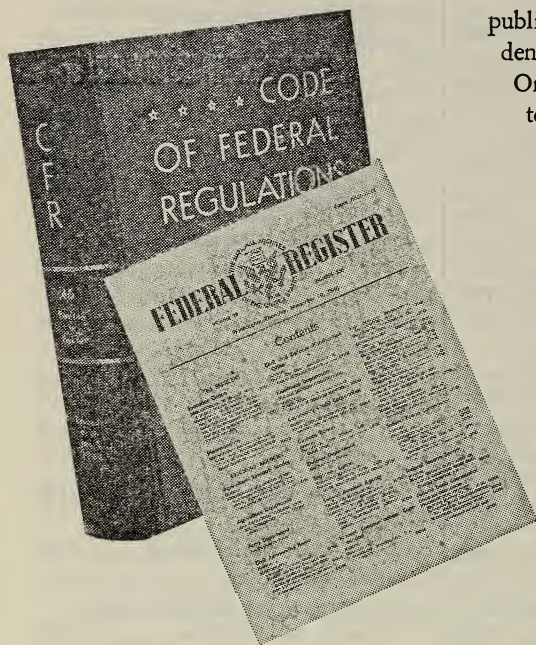
	N.J. No.		N.J. No.
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Pep-O-Vite tablets and Super		Mathison Electropsychometer_	7808
Instá Protein Wafers-----	7801	<i>See also</i> Arcon Manufactur-	
Granchel Medicine Co., Inc.:		ing Co.	
coal-tar colors -----	7812	Mayhew, Mrs. M. C.:	
Grellva, Inc.:		Swedex massage machine-----	7836
Imperial Bee Cream With		Michelson, Herman:	
Royal Jelly and Age-Less		imitation Diuril tablets-----	7813
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Helauni's Cosmetics:		C-112 Wetting Solution-----	7817
Helauni's Ultra Wrinkle Night		Miller Chemical Co.:	
Cream and Wonder Lotion--	7832	Millers hog and poultry wormer	
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Hilly Medicinal Products, Inc.:		Sunflo Air Purifier-----	¹ 7834
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Hollender, S. S., Inc.:		Sargon Pills and Uarginin	
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Hypnosophic Institute. <i>See</i> Cop-		Nap-A-Night. <i>See</i> Manusia,	
ley, Bernard and Roseman,		Douglas.	
Bernard.		Norex Laboratories, Inc.:	
Johnston Hearing Aid & Elec-		Amitone tablets-----	² 7823
tronics Co., Inc.:		Nu-Age Biorganic Products:	
Sleep-machine device and ac-		various dietary supplements--	7801
cessories -----	7810	Nutri-Bio Corp.:	
Johnston Sleep Machine Co. <i>See</i>		Nutri-Bio-food supplement----	7816
Johnston Hearing Aid & Elec-		Pace Pharmacal Co., Inc.:	
tronics Co., Inc.		Prenatal tablets -----	7792
Justice Enterprises, Inc.:		Park Drug Co.:	
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K V Pharmacal Co.:		Park Laboratories:	
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Kegan Research Laboratories,		Cal-Re-Low dietary supple-	
Inc.:		ment -----	7825
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tion -----	³ 7783	various animal tissues and dis-	
Lady Ample, Inc.:		tilled water-----	7784
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Manusia, Douglas:		of Textron, Inc.:	
Sleep-machine device and		Medicated Super Egg Atoms	
accessories -----	7810	feed -----	7821

¹ (7834) Seizure contested. Contains opinion of the court.² (7823) Seizure contested.³ (7782, 7783, 7789, 7793, 7794, 7803) Injunction issued.

	N.J. No.		N.J. No.
Radex Corp.:		Thompson Drug Co.:	
negative ion generator-----	7835	various prescription drugs-----	7787
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Roseman, Bernard:		tions -----	³ 7793
LSD (D-lysergic acid diethyla-		Thorson's Soap Lake Products Co.	
mide) -----	7785	See Thorson, Roxie.	
Royal Products:		Toftness Chiropractic Clinic:	
rubber prophylactics -----	7818	Research Model devices-----	7807
Saine, H. T.:		Union Mattress & Pillow Co.:	
various devices -----	³ 7803	Vibra-Matic mattress-----	7809
Sarkisian, Kegan:		Val-A Co.:	
KC 555 and KC 555 Prepara-		phenothiazine powder and Val-	
tion -----	³ 7783	A phenothiazine -----	7811
Schaeffer Products Co., Inc.:		Vanguard Pharmaceutical Corp.:	
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Schmidt, W. F.:		sion -----	³ 7794, 7795
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Sugarlogics Southern Corp.:		Walgreen Co.:	
Dextra Sugar-----	7824	Sul-Ray mineral baths-----	7833
Sugarlogics World Corp.:		Weiner, J., & Co.:	
Dextra Sugar-----	7824	various prescription drugs-----	7790
Sulray, Inc.:		Western Serum Co.:	
Sul-Ray mineral baths-----	7833	corticotropin gel injection and	
Superior Pharmacal Corp.:		vitamin B ₁₂ injection-----	7822
Supainex capsules and Supab-			
Na-Sal tablets-----	7800		

³ (7782, 7783, 7789, 7793, 7794, 7803) Injunction issued.

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D.D.N.J., F.D.C. 7841-7880

JAN 5 - 1965

CURRENT SERIAL RECORDS

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

7841-7880

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b) (1), and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*
WASHINGTON, D.C., November 24, 1964.

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VIOLATIVE SALES OF PRESCRIPTION DRUGS

7841. (F.D.C. No. 46670. S. Nos. 67-827 R, 68-442 R, 68-445 R.)

INFORMATION FILED: 1-30-62, E. Dist. Tex., against Albert V. Clawson, t/a Clawson Dairiette, DeKalb, Tex.

CHARGE: Between 3-1-61 and 4-18-61, *amphetamine sulfate tablets* were dispensed twice and *dextro-amphetamine sulfate capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2-9-62. \$300 fine.

7842. (F.D.C. No. 48515. S. Nos. 15-305/13 V, 15-557/8 V.)

INFORMATION FILED: 11-30-62, M. Dist. Tenn., against John A. McGee (employee of a drug firm), Nashville, Tenn., and Jack C. Hailey.

CHARGE: Between 11-15-62 and 11-21-62, *amphetamine sulfate tablets* (counts 5, 6, 7, 8, and 9) were dispensed 5 times, *methamphetamine hydrochloride tablets* (counts 1, 2, 10, and 11) were dispensed 4 times, and *dextro-amphetamine sulfate tablets* (count 4) and *tablets containing a mixture of dextro-amphetamine sulfate and amphetamine sulfate* (count 3) were each dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: On 4-16-63, the case came on for trial before the court, and on 4-22-63, the court found McGee not guilty on counts 4, 5, 6, and 7, and guilty on counts 1, 2, 3, 8, and 9, and Hailey guilty on counts 10 and 11. On 4-29-63, Hailey was sentenced to 6 months' imprisonment and McGee was sentenced to 1½ years' imprisonment.

7843. (F.D.C. No. 49194. S. Nos. 22-741 V, 22-747 V, 22-749 V, 22-753 V, 22-755 V, 22-757 V.)

INFORMATION FILED: 12-10-63, Dist. N. Mex., against Mobil Truck Stop (a partnership), Las Cruces, N. Mex., George H. Sanders (partner and general manager), James H. Miller, James L. Hudman, and Ernest B. Tolman (employees).

CHARGE: Between 2-7-63 and 4-8-63, *amphetamine sulfate tablets*, and *capsules containing a mixture of amobarbital and dextro-amphetamine sulfate* were each dispensed 3 times without a prescription.

PLEA: Guilty by the partnership and Sanders to 2 counts each; by Hudman, Tolman, and Miller to 1 count each.

DISPOSITION: 1-30-64. Hudman—1 year in prison, 9 months of which was suspended, and probation for 9 months; Tolman—probation for 1 year. 3-17-64. Miller—probation for 1 year. 4-6-64. Sanders—1 year in prison, 9 months of which was suspended, and probation for 1 year. 4-24-64. Partnership—\$500 fine.

7844. (F.D.C. No. 48201. S. Nos. 11-083 T, 11-085 T, 11-090 T, 11-093 T.)

INFORMATION FILED: 4-16-63, W. Dist. Pa., against Samuel Ralph Cohen, M.D., Pittsburgh, Pa.

CHARGE: Between 2-15-62 and 3-16-62, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 2-17-64. \$2,000 fine, plus costs, and probation for 6 months.

7845. (F.D.C. No. 49542. S. Nos. 45-222 V, 45-225/26 V.)

INFORMATION FILED: 2-24-64, W. Dist. Ark., against Basil Beaty, Waldron, Ark.

CHARGE: Between 2-13-63 and 5-14-63, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 3-10-64. Sentence of probation for 1 year.

7846. (F.D.C. No. 49191. S. Nos. 55-784/86 V.)

INFORMATION FILED: 11-12-63, W. Dist. Okla., against Charles L. Harrington, Mesquite, Tex.

CHARGE: On 2-15-63, at Oklahoma City, Okla., *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 3-12-64. Imprisonment for 90 days.

7847. (F.D.C. No. 49878. S. Nos. 7-286 A, 7-291 A, 7-306 A, 7-309 A, 7-312 A.)

INFORMATION FILED: 4-2-64, E. Dist. S.C., against Stephen B. Kabala, of Jacksonville, Fla.

CHARGE: (Counts 1, 5, 9, 12, and 15.) Between 1-27-64 and 2-26-64, *amphetamine sulfate tablets*, *phenobarbital capsules*, *dextro-amphetamine sulfate capsules*, *secobarbital sodium capsules*, and *penicillin tablets* were each dispensed once without a prescription.

The defendant was also charged with similar violations in the other counts of the information.

PLEA: Not guilty to all counts.

DISPOSITION: On 5-25-64, the case came on for trial before court and jury.

On 5-26-64, after the Government's case had been presented and after some of the defendant's direct testimony had been presented, the defendant, with the permission of the court, withdrew his plea of not guilty and entered a plea of guilty on counts 1, 5, 9, 12, and 15. On 5-26-64, the court imposed a sentence against the defendant of 5 years in jail of which 3 years were to be served, 2 years suspended, and the defendant placed on probation for 3 additional years.

7848. (F.D.C. No. 49691. S. Nos. 15-084/5 X.)

INFORMATION FILED: 3-18-64, S. Dist. Ind., against James T. Pinto, Loogootee, Ind.

CHARGE: Between 7-25-63 and 8-2-63, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 6-10-64. \$100 fine, plus costs.

7849. (F.D.C. No. 45587. S. Nos. 83-823 P, 18-885/6 R, 18-968 R, 18-971/3 R, 18-975/6 R, 18-978/80 R.)

INFORMATION FILED: 6-14-61, W. Dist. Tex., against Mountain View Pharmacy, Inc., El Paso, Tex., and Armando Del Rio (president).

CHARGE: Between 2-17-60 and 5-24-60, *dextro-amphetamine sulfate capsules* were dispensed 4 times and *penicillin tablets* were dispensed twice without a prescription, *meprobamate tablets* were dispensed 4 times, *penicillin tablets* and *penicillin capsules* were each dispensed once, upon requests for prescription refills without obtaining authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 9-7-61. Corporation—\$1 fine; individual—6 years' imprisonment suspended.

7850. (F.D.C. No. 48571. S. No. 19-661 V.)

INFORMATION FILED: 3-31-63, E. Dist. Tex., against Frank J. Penny, Sulphur Springs, Tex.

CHARGE: On 9-19-62, *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 1-3-64. Probation for 1 year.

7851. (F.D.C. No. 47854. S. No. 48-147 R.)

INFORMATION FILED: 4-23-63, E. Dist. Mich., against Elmer H. Chilton (partner in a pharmacy), and Phelps T. Chilton (employee), Detroit, Mich.

CHARGE: On 3-24-61, *dextro-amphetamine sulfate tablets* were dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 2-6-64. Each defendant—\$250 fine, and probation for 2 years.

7852. (F.D.C. No. 48899. S. Nos. 66-761 T, 66-763/64 T, 66-767/68 T.)

INFORMATION FILED: 8-2-63, N. Dist. Ohio, against Charles E. Kinsey, t/a Tiny's Truck Stop, Oceola, Ohio, and B. Jeanne Kinsey.

CHARGE: Between 4-24-62 and 10-2-62, *tablets containing a mixture of dextro-amphetamine sulfate and amobarbital* were dispensed once and *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty by Charles Kinsey to 5 counts; by B. Jeanne Kinsey to 1 count.

DISPOSITION: 9-6-63. Charles Kinsey—5 years' probation. 4-10-64. B. Jeanne Kinsey—3 years' probation.

7853. (F.D.C. No. 49172. S. Nos. 29-364/5 V.)

INFORMATION FILED: 11-8-63, W. Dist. Mo., against James F. Dougherty (a partner in Dougherty Bros. Medical Art Center).

CHARGE: Between 12-7-62 and 12-11-62, *Equanil tablets* and *Dexedrine Sulfate capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 1-24-64. \$200 fine.

7854. (F.D.C. No. 48569. S. No. 66-867 T.)

INFORMATION FILED: 6-28-63, E. Dist. Mich., against F. Dean Mann, t/a Dean Mann Drug Store, Highland Park, Mich.

CHARGE: On 5-29-62, *Equanil tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 3-26-64. \$1,000 fine, 1 year in prison suspended, and probation for 2 years.

7855. (F.D.C. No. 49134. S. Nos. 15-080 V, 15-083/6 V, 15-088/9 V, 15-091/3 V, 15-095/6 V.)

INFORMATION FILED: 9-10-63, E. Dist. Ky., against Charles E. Skaggs, t/a The Lawrence Drug Store, Louisa, Ky.

CHARGE: Between 12-14-62 and 1-22-63, *meprobamate tablets* were dispensed 7 times, *thyroid tablets* and *Dexedrine Sulfate tablets* were each dispensed twice, and *chlorothiazide tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12-2-63. \$540 fine.

7856. (F.D.C. No. 49873. S. Nos. 18-342/3 X, 18-384/5 X, 69-861/2 X.)

INFORMATION FILED: 5-11-64, W. Dist. Okla., against Vee Drug Co. (a corporation), Cushing, Okla., and Lawrence L. Marx (vice president).

CHARGE: Between 6-26-63 and 9-12-63, *meprobamate tablets* were dispensed 3 times, *Serpasil tablets* were dispensed twice, and *Achromycin capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6-26-64. Corporation—\$60 fine; Marx—\$300 fine.

7857. (F.D.C. No. 48576. S. No. 25-024 T.)

INFORMATION FILED: 7-3-63, E. Dist. Mich., against Sanford E. Linsky (pharmacist), Plymouth, Mich.

CHARGE: On 1-31-62, *Miltown tablets* were dispensed once without a prescription.

PLEA: Nole contendere.

DISPOSITION: 4-15-64. \$100 fine and probation for 2 years.

7858. (F.D.C. No. 49178. S. Nos. 86-012 V, 86-021 V, 86-028 V, 86-161 V, 2-403 X.)

INFORMATION FILED: 1-16-64, S. Dist. Fla., against Ralph J. Wasserman and Benjamin Saks (pharmacists), Miami, Fla.

CHARGE: Between 4-25-63 and 6-4-63, *Miltown tablets* were dispensed 4 times and *penicillin tablets* were dispensed once without a prescription.

PLEA: Guilty by Wasserman to 3 counts; by Saks to 2 counts.

DISPOSITION: 3-20-64. Wasserman—\$900 fine, and probation for 18 months; Saks—\$1,000 fine, and probation for 18 months.

7859. (F.D.C. No. 49188. S. Nos. 86-015 V, 86-020 V, 86-031/32 V.)

INFORMATION FILED: 1-16-64, S. Dist. Fla., against San Antonio Drugs, Inc., Miami, Fla., Raul De La Torre (president), and Jose Ramon De La Torre (vice president).

CHARGE: Between 4-27-63 and 5-27-63, *penicillin tablets* and *pentobarbital sodium capsules* were each dispensed twice without a prescription.

PLEA: Guilty by each defendant to 2 counts.

DISPOSITION: 3-27-64. Corporation—\$600 fine; individual—\$600 fine, and probation for 2 years.

7860. (F.D.C. No. 48568. S. Nos. 56-881 T, 56-883/4 T, 56-886 T, 56-888 T, 56-890 T.)

INFORMATION FILED: 2-7-64, N. Dist. Tex., against Walter Lee Williams (pharmacist), Dallas, Tex.

ALLEGED VIOLATION: Between 2-12-62 and 3-15-62, *penicillin tablets* and *prednisone tablets* were each dispensed twice, and tablets of *penicillin with*

triple sulfa and *Chloromycetin capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4-17-64. \$500 fine, and probation for 2 years.

7861. (F.D.C. No. 47322. S. Nos. 18-425 T, 18-609 T.)

INDICTMENT RETURNED: 9-25-62, N. Dist. Tex., against Republic Drugs, Inc., Dallas, Tex., Harry L. Feffer (president), Thomas O. Hall (pharmacist), and Wilford U. Meyers (employee), of the corporation.

CHARGE: Between 8-22-61 and 8-29-61, *tablets of penicillin with triple sulfa* and *prednisone tablets* were each dispensed once without a prescription.

PLEA: Nolo contendere by Hall to dispensing the *tablets of penicillin with triple sulfa* and by the other defendants to dispensing the *prednisone tablets*.

DISPOSITION: 10-26-62. Fines of \$250 against the corporation, \$200 against Feffer, and \$100 against Meyers. 10-22-63. Fine of \$100 against Hall.

7862. (F.D.C. No. 49165. S. Nos. 15-101/11 V.)

INFORMATION FILED: 10-22-63, E. Dist. Ky., against Gorman C. Croley (pharmacist), Pineville, Ky.

CHARGE: Between 1-11-63 and 3-19-63, *prednisone tablets* were dispensed 4 times, *Diuril tablets* were dispensed 3 times, and *thyroid tablets* and *Equanil tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 4-9-64. \$550 fine, plus costs, with \$300 of the fine suspended.

7863. (F.D.C. No. 49186. S. Nos. 65-315/16 V, 65-318/22 V.)

INFORMATION FILED: 12-18-63, M. Dist. Tenn., against James R. Mansfield, Jr., t/a Mansfield Drug Store, Nashville, Tenn.

CHARGE: Between 4-9-63 and 4-30-63, *prednisone tablets*, *Diuril tablets*, and *thyroid tablets*, were each dispensed twice, and *Meticorten tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 5-4-64. 32 months' imprisonment suspended, \$3,500 fine suspended, and probation for 3 years.

7864. (F.D.C. No. 49548. S. Nos. 13-822/6 V.)

INFORMATION FILED: 3-3-64, N. Dist. Ill., against Armin P. Maag, t/a Armin's Pharmacy, Chicago, Ill., and Margaret C. Barski (pharmacist).

CHARGE: Between 1-10-63 and 1-31-63, *Seconal Sodium capsules* were dispensed twice, *Dexedrine Sulfate capsules* were dispensed twice, and *Dexedrine Sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 6-23-64. Maag—\$500 fine, plus costs, and probation for 2 years; Barski—probation for 2 years.

7865. (F.D.C. No. 49171. S. Nos. 53-687/88 V.)

INFORMATION FILED: 12-20-63, Dist. Oreg., against Bertha Mayer Holtzman, t/a The Prescription Shop, Portland, Oreg., and Clair Andrew Van Riper (pharmacist).

CHARGE: On 1-4-63, *Seconal Sodium capsules* and *Nembutal Sodium capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2-26-64. Each defendant—\$2,000 fine, and probation for 1 year.

7866. (F.D.C. No. 48897. S. Nos. 9-163 V, 9-165/7 V.)

INFORMATION FILED: 10-14-63, W. Dist. Pa., against *Speicher-Grady Drug Co.* (a corporation), *Johnstown, Pa.*, and *William D. Grady* (secretary-treasurer).

CHARGE: Between 11-6-62 and 12-18-62, *Seconal Sodium capsules* were dispensed 4 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 12-27-63. Corporation—\$400 fine, plus costs; Grady—\$4 fine.

7867. (F.D.C. No. 42495. S. Nos. 32-994/S P, 57-S62/3 P, 57-S65 P, 73-328/30 P.)

INFORMATION FILED: 6-6-62, S. Dist. N.Y., against *Hunter Pharmacy, Inc.*, *Isaac Wagman* (president), and *Sidney Silver* (vice president), *New York, N.Y.*

CHARGE: Between 1-27-59 and 8-20-59, *Seconal Sodium capsules* (counts 1, 2, 3, 6, and 7) were dispensed 5 times, *Dexedrine Spansule capsules* (counts 4, 5, and 8) were dispensed 3 times and *Miltown tablets* (counts 9, 10, and 11) were dispensed 3 times upon requests for prescription refills without authorization from the prescriber.

PLEA: Not guilty.

DISPOSITION: On 1-22-63, the defendants having moved to dismiss the information, the court rendered the following opinion (213 F. Supp. 323):

WEINFELD, *District Judge*: "The Court has fully considered the extensive and somewhat discursive affidavits and voluminous briefs submitted in support of the defendants' motion to dismiss the information.

"The defense of entrapment cannot be sustained as a matter of law since it is too obvious for discussion that a factual issue exists.

"The claim of denial of due process and deprivation of constitutional rights is equally lacking in substance. Although section 305 of the Federal Food, Drug, and Cosmetic Act¹ does not require as a prerequisite to criminal prosecution that an alleged violator be given 'an opportunity to present his views,' such opportunity was granted to the defendants in the instant case.² This, however, did not require a full dress trial with all the formal attributes thereof, but a fair opportunity to present their views. The record indicates that they were given reasonable notice of the alleged violations; they appeared by counsel; they not only presented their views thereat, but subsequently submitted an extensive written statement containing substantially all the matters adverted to in their lengthy affidavits on this motion, much of it of emotional content which serves no purpose as far as this motion is concerned.

"The defendants claim that the failure of the administrative agency to implement section 306 of the Act is a denial of due process.³ With respect to 'minor violations,' the Secretary of Health, Education, and Welfare, where he believes a warning to the violator is sufficient to safeguard the public interest, is not required to report the matter for prosecution. The determination of whether a violation is of such a nature as not to require criminal prosecution to vindicate the public interest is entrusted to the judgment of the Secretary. In the instant case, the reference of the matter to the United States Attorney for prosecution is indication that he deems the offenses as other than 'minor,' or that he believes the public interest will not be adequately safeguarded by a warning. The statute nowhere commands, with respect to this section, that

¹ 21 U.S.C. § 335 (1958).

² *United States v. Dotterweich*, 320 U.S. 277, 64 S. Ct. 134, 88 L. Ed. 48 (1943).

³ 21 U.S.C. § 336 (1958).

he establish rules and regulations for procedures to determine whether a warning instead of a prosecution or injunction serves to vindicate the public interest. The statute itself indicates the matter rests in his discretion.

"As to the defendants' contention that their constitutional right to a speedy trial has been denied, it appears the information was filed on June 6, 1962, and the present motion made fast upon its heels. The real burden of their complaint is that the offense occurred in 1959 and the information was not filed until almost three years after a hearing was granted them under section 305. While it appears that the matter moved through channels at a leaden-footed pace, the prosecution was commenced well within the statutory period of limitations. Obviously, until the information was filed, the defendants were in no position to demand that it be proceeded with, and thus bring themselves within the rule in this Circuit that a defendant seeking a dismissal of an indictment or information for lack of a speedy trial is required to exert efforts to accelerate the proceedings.⁴ Assuming arguendo that the failure to file an information within a reasonable time after the facts are known to administrative and prosecuting authorities furnishes a basis for an appropriate motion, either under the Sixth Amendment to the Federal Constitution, or under Rule 48(b) of the Federal Rules of Criminal Procedure, the defendants, upon the facts here presented, have not made a showing of prejudice.⁵ It does not appear that Horowitz or any other person who may have knowledge of the facts and whose testimony is material in support of the defense is presently or will be unavailable for trial, if indeed the defendants plan to call any of them.

"This aspect of the motion is denied without prejudice to a renewal upon the trial, where the issues may be fully presented and a determination made against the background of the trial as to whether or not in fact, by reason of inability to obtain witnesses, or for other reasons, the delay has been prejudicial to the defendants in meeting the charges against them.⁶

"The Court has considered all other contentions of the defendants and likewise finds them wanting.

"The motion is denied as indicated herein."

On 5-27-63, the case came on for trial before court and jury. On 5-31-63, the jury rendered a verdict of guilty against the defendants. On 6-27-63, the court fined the corporation \$1,650; Wagman \$350; and Silver \$200.

7868. (F.D.C. No. 45243. S. Nos. 9-343 R, 9-345 R, 9-347 R, 9-523/4 R, 9-661/5 R.)

INFORMATION FILED: 4-12-61, W. Dist. N.Y., against John W. Dunne, t/a Dunne's Pharmacy, Buffalo, N.Y.

CHARGE: Between 3-13-60 and 5-17-60, *Tuinal capsules* were dispensed 3 times and *Seconal Sodium capsules* were dispensed twice upon requests for a prescription refill without authorization from the prescriber; *AM Plus capsules* were dispensed twice, *Compazine tablets* were dispensed twice, and *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 5-25-64. \$500 fine.

7869. (F.D.C. No. 45247. S. Nos. 9-331/5 R, 9-338/9 R, 9-385 R, 9-387 R, 9-543/4 R, 9-546 R.)

INFORMATION FILED: 4-12-61, W. Dist. N.Y., against Dante Joseph LoBue, Buffalo, N.Y.

CHARGE: Between 4-26-60 and 5-28-60, *Tuinal capsules* were dispensed twice and *Seconal Sodium capsules* were dispensed 3 times upon requests for a pre-

⁴ *United States v. Lustman*, 258 F. 2d 475, 478 (2d Cir.), cert. denied, 358 U.S. 880, 79 S. Ct. 118, 3 L. Ed. 2d 109 (1958); *United States v. Kaufman* (2 Cir., 1963), 311 F. 2d 695.

⁵ Compare *United States v. Brown*, 188 F. Supp. 624 (S.D.N.Y. 1960).

⁶ See *United States v. Dillon*, 183 F. Supp. 541 (S.D.N.Y. 1960).

scription refill without authorization from the prescriber; *AM Plus capsules* were dispensed twice, *Dexedrine Sulfate tablets* were dispensed 3 times, and *Compazine tablets* were dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 5-25-64. \$500 fine.

7870. (F.D.C. No. 49137. S. Nos. 9-183 V, 9-185 V, 9-188 V, 9-189 V.)

INFORMATION FILED: 10-4-63, W. Dist. Pa., against Nathan Florman, t/a Stanton-Negley Drug Co., Pittsburgh, Pa.

RESULTS OF INVESTIGATION: Investigation showed that the *secobarbital sodium capsules* and *pentobarbital sodium capsules* had been fabricated at Verona, Pa., using, respectively, *secobarbital sodium powder*, and *pentobarbital sodium powder*, which had been shipped in interstate commerce.

CHARGE: Between 10-26-62 and 1-31-63, *Tuinal capsules* were dispensed twice, and *secobarbital sodium capsules* and *pentobarbital sodium capsules* were each dispensed once, upon requests for prescription refills without obtaining authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 12-27-63. \$400 fine, plus costs.

7871. (F.D.C. No. 49156. S. Nos. 5-027 V, 5-031 V, 5-035 V, 5-189/90 V, 5-192 V.)

INFORMATION FILED: 12-3-63, Dist. Md., against Nathan N. Cooper, t/a Parkville Pharmacy, Parkville, Md., and Edward N. Watts (pharmacist).

CHARGE: Between 11-24-62 and 1-28-63, *Biphetamine capsules* were dispensed 3 times and *Dexedrine Sulfate tablets* were dispensed once upon requests for prescription refills without authorization by the prescriber, and *penicillin tablets* were dispensed twice without a prescription.

PLEA: Nolo contendere by Watts to 1 count involving *penicillin tablets* and to 2 counts involving *Biphetamine capsules*, and by Cooper to 3 counts, one each involving *penicillin tablets*, *Biphetamine capsules* and *Dexedrine Sulfate tablets*.

DISPOSITION: 4-10-64. Cooper—\$1,500 fine, probation for 2 years; Watts—\$750 fine, probation for 2 years.

7872. (F.D.C. No. 49181. S. Nos. 8-223/4 V, 8-242/6 V, 8-943/5 V.)

INFORMATION FILED: 1-16-64, Dist. Mass., against Edward R. Rosen, t/a Norcross Drug, Medford, Mass.

CHARGE: Between 3-6-63 and 4-1-63, *Butazolidin tablets* were dispensed 3 times and *Dexedrine Spansule capsules* were dispensed twice upon requests for prescription refills without authorization by the prescriber, and *Miltown tablets* were dispensed 3 times and *phenobarbital tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 6-29-64. \$1,000 fine, and probation for 2 years.

7873. (F.D.C. No. 45999. S. Nos. 9-556/9 R, 10-184/90 R.)

INFORMATION FILED: 9-29-61, W. Dist. N.Y., against Smith's Pharmacy (a partnership), Buffalo, N.Y., and Allen H. Smith (partner).

CHARGE: Between 10-27-60 and 12-13-60, *Dexedrine Sulfate tablets* were dispensed 4 times and *pentobarbital sodium capsules* were dispensed 7 times upon requests for prescription refills without authorization from the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 5-25-64. \$500 fine against the defendants jointly.

7874. (F.D.C. No. 49160. S. Nos. 62-935 R, 63-907 R.)

INFORMATION FILED: 11-4-63, S. Dist. Ohio, against Willie James Stallworth, Columbus, Ohio.

CHARGE: Between 7-31-61 and 8-7-61, *desoxyephedrine hydrochloride tablets* were dispensed twice without a prescription.

PLEA: Not guilty.

DISPOSITION: On 2-24-64, the case came on for trial before court and jury, and on 2-26-64, the jury returned a verdict of guilty on 1 count and not guilty on the other count. On 3-16-64, defendant was sentenced to probation for 5 years.

7875. (F.D.C. No. 49177. S. Nos. 14-984 T, 14-992 T.)

INFORMATION FILED: 1-22-64, N. Dist. Ill., against Pulaski Pharmacy, Inc., Chicago, Ill., and Francis V. Krestan (president-pharmacist).

CHARGE: Between 6-26-62 and 8-22-62, *Fiorinal tablets* and *dextro-amphetamine sulfate capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 3-31-64. \$600 fine, and costs against the defendants jointly.

7876. (F.D.C. No. 48145. S. Nos. 40-385/7 T.)

INFORMATION FILED: 11-30-62, S. Dist. N.Y., against Chelsea Community Pharmacy (a partnership), New York, N.Y., and Jonas Friedman (partner).

CHARGE: Between 10-6-61 and 10-18-61, *Halotestin tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 2-15-63. Partnership—\$150 fine; individual—probation for 6 months.

7877. (F.D.C. No. 49168. S. Nos. 3-061 V, 3-063 V.)

INFORMATION FILED: 11-20-63, E. Dist. N.C., against Newton Grove Drug Co., Inc., Alton S. Parrish (president), and Stephen C. Morris (vice president), Newton Grove, N.C.

CHARGE: Between 2-8-63 and 2-13-63, *Terramycin capsules* were dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 5-22-64. Corporation—\$500 fine; each individual—\$500 fine, and 2 years' probation.

7878. (F.D.C. No. 43695. S. Nos. 10-364/5 P, 10-367 P, 10-374 P, 10-377 P, 10-878 P, 10-893 P, 11-142 P, 11-144 P, 11-150 P, 11-157 P.)

INFORMATION FILED: 12-3-59, W. Dist. N.Y., against Charles C. Parisi, t/a Hopper's Pharmacy, Buffalo, N.Y.

CHARGE: Between 2-16-59 and 4-15-59, *Thorazine tablets* were dispensed 4 times and *paraldehyde* was dispensed 3 times upon requests for prescription

refills without authorization by the prescriber, and *Benzedrine Sulfate tablets* and *Citramine Racemic tablets* were dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 5-25-64. \$500 fine.

7879. (F.D.C. No. 48873. S. Nos. 90-769/70 T.)

INFORMATION FILED: 2-14-64, N. Dist. Tex., against Sun Drugs, Inc., Dallas, Tex., and Sol H. Kaplan (vice president), Robert L. Periman, and Talmadge A. Sparks (pharmacists).

CHARGE: Between 9-2-62 and 9-11-62, *pentobarbital sodium capsules* were dispensed twice upon request for prescription refills without authorization from the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 6-18-64. Corporation and Kaplan—\$1,000 fine jointly; Periman and Sparks—\$100 fine each, and probation for 1 year.

7880. (F.D.C. No. 47099. S. No. 84-644 R.)

INFORMATION FILED: 5-3-62, Dist. N.J., against Jerome Gallichio, Jr., Newark, N.J.

CHARGE: On 7-7-61, *secobarbital sodium capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12-20-63. Imprisonment for 1 year.

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¹ (7842, 7847, 7874) Prosecution contested.

² (7867) Prosecution contested. Contains opinion of the court.

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Clawson Dairiette. <i>See</i> Clawson, A. V.		amphetamine sulfate tablets-----	7868
Cohen, S. R. (M. D.):		Dunne's Pharmacy. <i>See</i> Dunne, J. W.	
amphetamine sulfate tablets--	7844	Feffer, H. L.:	
Cooper, N. N.:		tablets of penicillin with triple	
Biphetamine capsules, Dexe-		sulfa and prednisone tablets-----	7861
drine Sulfate tablets, and		Florman, Nathan:	
penicillin tablets-----	7871	Tuinal capsules, secobarbital	
Croley, G. C.:		sodium capsules, and pento-	
prednisone tablets, Diuril tablets, thyroid tablets, and		barbital sodium capsules---	7870
Equanil tablets-----	7862	Friedman, Jonas:	
De La Torre, J. R.:		Halotestin tablets-----	7876
penicillin tablets and pento-		Gallichio, Jerome, Jr.:	
barbital sodium capsules----	7859	secobarbital sodium capsules--	7880

¹ (7842, 7847, 7874) Prosecution contested.² (7867) Prosecution contested. Contains opinion of the court.

	N.J. No.		N.J. No.
Grady, W. D.:		Kinsey, C. E.:	
Seconal Sodium capsules-----	7866	tablets containing a mixture of	
Hailey, J. C.:		dextro-amphetamine sulfate	
amphetamine sulfate tablets,		and amobarbital, and am-	
methamphetamine hydro-		phetamine sulfate tablets---	7852
chloride tablets, dextro-		Krestan, F. V.:	
amphetamine sulfate tablets,		Fiorinal tablets and dextro-	
and tablets containing a mix-		amphetamine sulfate cap-	
ture of dextro-amphetamine		sules -----	7875
sulfate and amphetamine		Lawrence Drug Store. <i>See</i>	
sulfate -----	¹ 7842	Skaggs, C. E.	
Hall, T. O.:		Linsky, S. E.:	
tablets of penicillin with triple		Miltown tablets-----	7857
sulfa and prednisone tab-		LoBue, D. J.:	
lets -----	7861	Tuinal capsules, Seconal Sodi-	
Harrington, C. L.:		um capsules, AM Plus cap-	
amphetamine sulfate tablets--	7846	sules, Dexedrine Sulfate tab-	
Holtzman, B. M.:		lets, and Compazine tablets--	7869
Seconal Sodium capsules and		McGee, J. A.:	
Nembutal Sodium capsules--	7865	amphetamine sulfate tablets,	
Hopper's Pharmacy. <i>See</i> Parisi,		methamphetamine hydro-	
C. C.		chloride tablets, dextro-	
Hudman, J. L.:		amphetamine sulfate tablets,	
amphetamine sulfate tablets		and tablets containing a mix-	
and capsules containing a		ture of dextro-amphetamine	
mixture of amobarbital		sulfate and amphetamine	
and dextro-amphetamine		sulfate -----	¹ 7842
sulfate -----	7843	Maag, A. P.:	
Hunter Pharmacy, Inc.:		Seconal Sodium capsules, Dexe-	
Seconal Sodium capsules,		drine Sulfate capsules, and	
Dexedrine Spansule cap-		Dexedrine Sulfate tablets---	7864
sules, and Miltown tablets--	² 7867	Mann, F. D.:	
Kabala, S. B.:		Equanil tablets-----	7854
amphetamine sulfate tablets,		Mann, Dean, Drug Store. <i>See</i>	
phenobarbital capsules, dex-		Mann, F. D.	
tro-amphetamine sulfate cap-		Mansfield, J. R., Jr.:	
sules, secobarbital sodium		prednisone tablets, Diuril tab-	
capsules, and penicillin tab-		lets, thyroid tablets, and	
lets -----	¹ 7847	Meticorten tablets-----	7863
Kaplan, S. H.:		Mansfield Drug Store. <i>See</i> Mans-	
pentobarbital sodium cap-		field, J. R., Jr.	
sules -----	7879	Marx, L. L.:	
Kinsey, B. J.:		meprobamate tablets, Serpasil	
tablets containing a mixture of		tablets, and Achromycin cap-	
dextro-amphetamine sulfate		sules -----	7856
and amobarbital, and am-		Meyers, W. U.:	
phetamine sulfate tablets---	7852	tablets of penicillin with triple	
		sulfa and prednisone tab-	
		lets -----	7861

¹ (7842, 7847, 7874) Prosecution contested.² (7867) Prosecution contested. Contains opinion of the court.

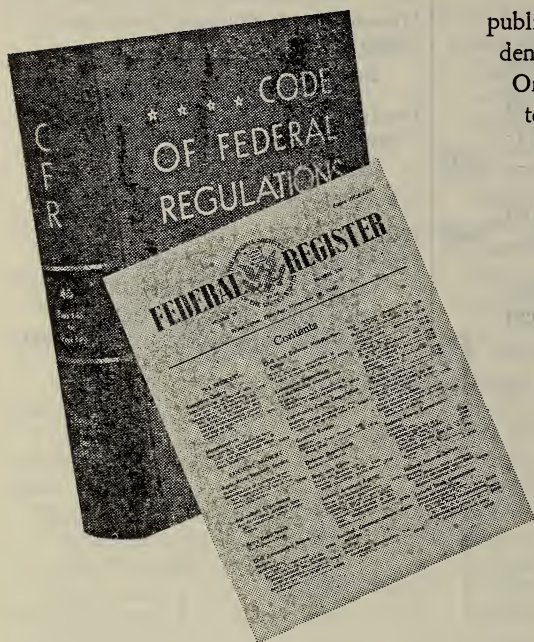
	N.J. No.		N.J. No.
Miller, J. H.:		Republic Drugs, Inc.:	
amphetamine sulfate tablets		tablets of penicillin with triple	
and capsules containing a		sulfa and prednisone tab-	
mixture of amobarbital and		lets -----	7861
dextro-amphetamine sul-		Rosen, E. R.:	
fate -----	7843	Butazolidin tablets, Dexedrine	
Mobil Truck Stop:		Spansule capsules, Miltown	
amphetamine sulfate tablets		tablets, and phenobarbital	
and capsules containing a		tablets -----	7872
mixture of amobarbital and		San Antonio Drugs, Inc.:	
dextro-amphetamine sul-		penicillin tablets and pento-	
fate -----	7843	barbital sodium capsules----	7859
Morris, S. C.:		Sanders, G. H.:	
Terramycin capsules-----	7877	amphetamine sulfate tablets	
Mountain View Pharmacy, Inc.:		and capsules containing a	
dextro-amphetamine sulfate		mixture of amobarbital and	
capsules, penicillin capsules,		dextro-amphetamine sulfate--	7843
penicillin tablets, and me-		Saks, Benjamin:	
probamate tablets-----	7849	Miltown tablets and penicillin	
Newton Grove Drug Co., Inc.:		tablets -----	7858
Terramycin capsules-----	7877	Silver, Sidney:	
Norcross Drug. <i>See</i> Rosen, E. R.		Seconal Sodium capsules,	
Parisi, C. C.:		Dexedrine Spansule cap-	
Thorazine tablets, paraldehyde,		sules, and Miltown tablets--	² 7867
Benzedrine Sulfate tablets,		Skaggs, C. E.:	
and Citramine Racemic tab-		meprobamate tablets, thyroid	
lets -----	7878	tablets, Dexedrine Sulfate	
Parkville Pharmacy. <i>See</i> Cooper,		tablets, and chlorothiazide	
N. N.		tablets -----	7855
Parrish, A. S.:		Smith, A. H.:	
Terramycin capsules-----	7877	Dexedrine Sulfate tablets and	
Penny, F. J.:		pentobarbital sodium cap-	
dextro-amphetamine sulfate		sules -----	7873
tablets -----	7850	Smith's Pharmacy:	
Periman, R. L.:		Dexedrine Sulfate tablets and	
pentobarbital sodium cap-		pentobarbital sodium cap-	
sules -----	7879	sules -----	7873
Pinto, J. T.:		Sparks, T. A.:	
amphetamine sulfate tablets--	7848	pentobarbital sodium capsules--	7879
Prescription Shop. <i>See</i> Holtz-		Speicher-Grady Drug Co.:	
man, B. M.		Seconal Sodium capsules-----	7866
Pulaski Pharmacy, Inc.:		Stallworth, W. J.:	
Fiorinal tablets and dextro-		desoxyephedrine hydrochloride	
amphetamine sulfate cap-		tablets -----	¹ 7874
sules -----	7875	Stanton-Negley Drug Co. <i>See</i>	
		Florman, Nathan.	

¹ (7842, 7847, 7874) Prosecution contested.² (7867) Prosecution contested. Contains opinion of the court.

	N.J. No.		N.J. No.
Sun Drugs, Inc.:		Wagman, Isaac:	
pentobarbital sodium capsules -----	7879	Seconal Sodium capsules,	
Tiny's Truck Stop. <i>See</i> Kinsey,		Dexedrine Spansule capsules, and Miltown tablets--	² 7867
C. E.			
Tolman, E. B.:		Wasserman, R. J.:	
amphetamine sulfate tablets		Miltown tablets and penicillin	
and capsules containing a		tablets -----	7858
mixture of amobarbital and			
dextro-amphetamine sulfate -----	7843	Watts, E. N.:	
Van Riper, C. A.:		Biphetamine capsules, Dextro-	
Seconal Sodium capsules and		drine Sulfate tablets, and	
Nembutal Sodium capsules--	7865	penicillin tablets-----	7871
Vee Drug Co.:			
meprobamate tablets, Serpasil		Williams, W. L.:	
tablets, and Achromycin		penicillin tablets, prednisone	
capsules -----	7856	tablets, tablets of penicillin	
		with triple sulfa, and Chlor-	
		omycetin capsules-----	7860

² (7867) Prosecution contested. Contains opinion of the court.

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